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DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1984

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

NINETY-EIGHTH CONGRESS

FIRST SESSION

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Department of Health and Human Services

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DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1984

TUESDAY, APRIL 5, 1983

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, D.C.

The subcommittee met at 8:30 a.m, in room SD–116, Dirksen Senate Office Building, Hon. Lowell P. Weicker, Jr. (chairman) presiding.

Present: Senator Weicker.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

STATEMENT OF MARGARET HECKLER, SECRETARY

ACCOMPANIED BY:
DALE SOPPER, ASSISTANT SECRETARY FOR MANAGEMENT AND BUDGET
THOMAS DONNELLY, ASSISTANT SECRETARY FOR LEGISLATION

OPENING STATEMENT

Senator WEICKER. Good morning. The hearing will come to order.

Today marks the subcommittee's first hearing on the fiscal 1984 budget requests of the Department of Health and Human Services. We are honored to have as the Department's first witness the Secretary of Health and Human Services, Margaret Heckler.

Mrs. Heckler, we welcome you and your staff. I am sure you already know that you face a formidable task in managing one of the largest departments in the Federal Government, with a budget approaching $300 billion when the social security trust funds are figured in.

Your toughest job is to make certain that the Department continues to extend a helping hand to those who depend on its services and programs in their daily battle for survival. With this in mind, I was glad to note recently that in talking to your employees, you said that the Department's answer to the budget problems it faces is "not less compassion."

You may need to remind yourself of those words in future days because the HHS budget the administration projects for fiscal 1984 shows something less than the requisite level of compassion.

I know you did not participate in the writing of this budget. It may even be the case that as a Member of Congress you voted against cuts you are now called upon to defend. This puts you in an awkward position. But this budget puts Congress in an even worse predicament because it will require substantial restorations if it is to be made whole.

I hope you can help us in this difficult task. Now I will be delighted to go ahead and have your opening statement, the full text of which will be included in the record, Madame Secretary.

Secretary HECKLER. Thank you, Mr. Chairman.

Mr. Chairman and members of the committee, I am delighted to appear before you today to discuss the President's fiscal year 1984 budget proposals for the Department of Health and Human Services.

During my 16 years in the Congress, I was on your side of the table asking the questions and expecting prompt and accurate answers. Now that I am in the executive branch, I intend to respond to you as much as possible in that way, but also to seek your support, and to be an active partner as we try to come to grips with seemingly impossible problems under conditions of limited resources.

Your experience with and insight regarding the Department's programs are extremely important to me, and I hope to hear from you often during my tenure as Secretary and, incidentally, I expect that.

As you are well aware, the recession has placed severe pressures on our Department. Without question, the most helpful and constructive action this administration can take to help meet these problems is to continue its efforts to reduce inflation, cut interest rates, and end the recession, which I believe has already begun.

As Secretary of HHS, I have to function within the overall context of needs balanced by restraints. Given that fact, however, I intend to focus not on the limitations we face, but on the opportunities that exist within those limitations. The challenge for my Department is to continue to provide services for those who need and deserve them.

To accomplish that goal, we must do three things.

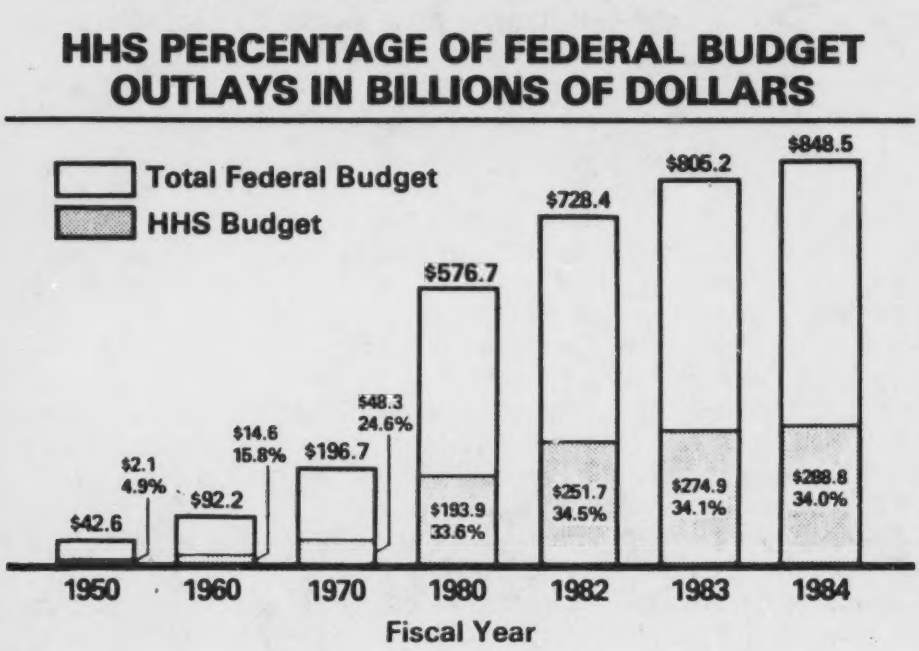
First, establish a clear set of priorities based on compassion and caring. I can tell you that my No. 1 priority is to maintain, wherever possible, services that directly help those who need help and cannot provide for themselves.

Second, we must aggressively encourage innovation and flexibility by the States and by ourselves. We have to be open to new ideas, new ways of doing things. In many cases, we can maintain current levels of care at less cost by doing things in a different, more effective way.

Third, we must encourage efficiency in our programs and work toward eliminating waste and fraud to the maximum extent possible. The better we do that job, the more money we will have available to help the needy.

I want to encourage the members of this committee and other Members of Congress to approach me with new ideas. As I said earlier, I am willing, and even anxious, to listen to them. And under my stewardship, the Department will be open to innovation.

Now dealing with the budget, I would like to present some charts.



[CHART 1]

HHS PERCENTAGE OF FEDERAL OUTLAYS

As you can see from chart 1, the fiscal year 1984 budget for the Department totals $289 billion in spending, nearly $14 billion more than in fiscal year 1983 and almost 50 percent higher than fiscal year 1980. It is the largest budget of any Government department and the third largest budget in the world, following the total U.S. budget and that of the Soviet Union.

Compared to total Government spending, HHS has received a rising share of the Federal budget over the years. Starting back in fiscal year 1950, this Department, including social security, received about 5 percent of the Federal budget, and in fiscal year 1960 that percentage was tripled, which is just incredible.

In fiscal year 1980 the HHS budget of $194 billion grew to 33.6 percent of the Federal budget. The $289 billion budget is projected to be 34 percent of the total in fiscal year 1984, $48 billion more than the defense budget.

As these figures demonstrate, the programs of this Department which protect the elderly, the disabled, the poor, and the sick have grown rapidly during the last four decades, during the last decade actually. Looking at the prior decade you see an incredible growth spiral.

Although the HHS budget continues to rise, this administration has succeeded in reducing the rapid growth rate of the 1970's. Between 1970 and 1980, the HHS budget has quadrupled, rising from $48 to $194 billion.

The policies of this administration have been to control these massive increases, which in large part resulted from double digit inflation rates experienced during the late 1970's. In 1984 the budget for HHS increases 5 percent, an increase which would keep pace with estimated inflation.

IMPACT ON BUDGET OF DECREASED INFLATION

The second chart is a very important one. This chart illustrates the success this administration has had in reducing inflation and its resulting effect on decreasing HHS outlays. This chart compares the President's fiscal year 1984 budget for HHS programs with what we estimate it would have been if the fiscal year 1981 inflation rate had prevailed during fiscal years 1982 through 1984.

When President Reagan took office, the inflation rate was 11.1 percent. The inflation rate for the last 12 months is now down to 3.5 percent, the lowest 12-month rate since 1972, when wage and price controls held down the inflation artificially.

This chart, I believe, indicates what has been done in the battle by the President to fight for a stable economy.

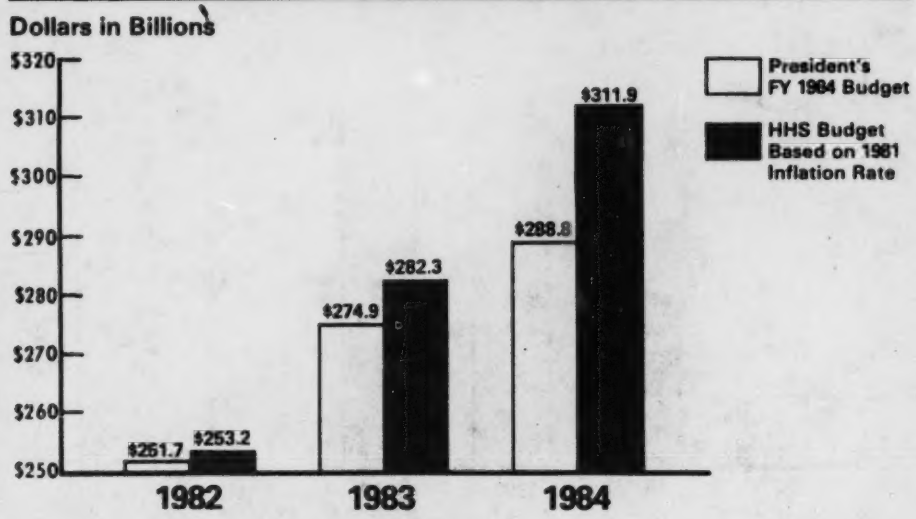
Reductions in inflation translate into outlay savings in our budget, since our entitlement programs—the largest being, of course, social security—are directly related to and affected by inflation.

Had the fiscal year 1981 inflation rate continued, HHS outlays, under the same policies as reflected in the President's fiscal year 1984 budget, would have reached an estimated $312 billion, $23 billion more than has been projected for fiscal year 1984. This calculation excludes any inflationary adjustments for discretionary programs.

Mr. Chairman, I would say that this really is one of the most important points I can make. When you look at this growth, this 1981 inflation rate, this budget would have been $311.9 billion just because of inflation. In reducing that—in stopping the spiraling growth of inflation—what we are really doing is helping the poor.

Inflation picks the pockets of the poor, the elderly, the disabled, and the retired more than any of the rest of us, because there is almost no way that they can compensate. This not only reduces the cost of programs to the taxpayer but, indeed, benefits everyone in the whole society.

DECREASE IN INFLATION: IMPACT ON HHS BUDGET



[CHART 2]

HHS DISCRETIONARY AND ENTITLEMENT PROGRAMS

In chart 3, Mr. Chairman, we have a comparison of two general categories—entitlement programs and discretionary programs—which make up the HHS budget, and as you can see, the large growth in the budget results primarily from the rise in entitlement spending.

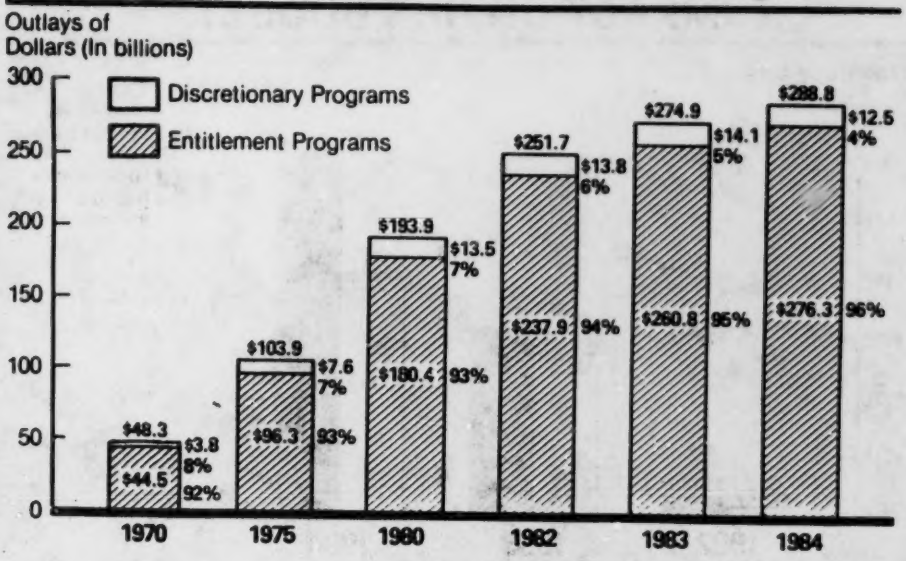
Between fiscal years 1970 and 1984, total HHS spending increased by $240.5 billion. Growth in the entitlement programs account for 96 percent of this increase, and the percentage of the HHS budget allocated to entitlement spending has increased from 92 percent in 1970 to 96 percent projected for 1984. On the other hand, spending for discretionary programs has grown from $3.8 billion in 1970 to $12.5 billion in 1984. As the entitlement program grows, sadly, some of the discretionary programs are being crowded out, and that is the dilemma that we face today.

This entitlement increase would have been even larger if it were not for the program changes proposed in this fiscal year 1984 budget to control costs. These changes are predicted to save $6.8 billion in 1984 outlays.

These entitlement reforms address two of the toughest long-term concerns in the Federal budget: Social security and rising health care costs.

I would like to take this opportunity to applaud the Congress in moving so quickly to approve the social security reform package and a prospective payment system for medicare. This system is a vital first step in injecting positive economic incentives into the health care system.

HHS Discretionary and Entitlement Programs



[CHART 3]

SUMMARY OF HHS BUDGET

Turning next to chart No. 4, this is a summary of the fiscal year 1984 budget by HHS Operating Division.

As I mentioned earlier, the HHS fiscal year 1984 budget totals $289 billion, about $14 billion, or 5 percent, above 1983. Over 95 percent of the entire budget represents spending by the Social Security and Health Care Financing Administrations.

SUMMARY OF FY 1984 BUDGET

	(Dollars in Billions)	
	Budget Authority	Outlays
Public Health Service	$ 7.7	$ 7.9
Health Care Financing Administration	80.9	80.7
Social Security Administration	191.1	194.7
Offices of Human Development Services and Community Services	5.3	5.3
Departmental Management/Other	0.2	0.2
Total, HHS	$285.2	$288.8

*FY 1984 HHS budget includes increases of $13.9 billion in outlays (5%) compared to 1983.

[CHART 4]

Now, I would like to highlight the HHS appropriations request for fiscal year 1984—chart 5. For the Department's programs considered by this subcommittee, our request totals $69.4 billion, about 25 percent of the total HHS budget.

FY 1984 BUDGET PROGRAMS CONSIDERED BY LABOR/ HHS SUBCOMMITTEE

(BUDGET AUTHORITY IN BILLIONS)

Public Health Service	$ 6.7
Health Care Financing Administration	38.1
Social Security Administration	19.0
Offices of Human Development Services and Community Services	5.3
Departmental Management	0.3
Total	$69.4

[CHART 5]

In addition, we are requesting $7.4 billion in advance appropriations for the first quarter of fiscal year 1985, primarily in the medicaid and aid to families with dependent children programs.

Included in our request are increases for discretionary programs which have long been a high priority of this subcommittee. For example: an additional $111 million for biomedical research activities of the National Institutes of Health and the Alcohol, Drug Abuse and Mental Health Administration; $21 million for the preventive health efforts of the Centers for Disease Control; and $62 million for Head Start, to provide services to an additional 29,100 disadvantaged children.

Finally, I would like to mention certain ongoing activities in the Department which seek to insure that the taxpayers' dollars are being put to the most appropriate and effective uses and that waste, fraud, and abuse is minimized.

In the Department's debt collection program, actual collections in fiscal year 1982 totaled $1.2 billion, $460 million more than in fiscal year 1981. Our goal for 1984 is $1.6 billion.

Initiatives to reduce fraud, waste, and abuse are tracked in the HHS management savings program.

The criminal investigations functions of the Social Security and Health Care Financing Administrations have been transferred to the Office of the Inspector General. By consolidating this staff, the Department's ability to combat fraud and abuse has been strengthened.

Actions such as these are critical to the effectiveness of this Department's programs, especially in times of limited resources. I intend to

place a high priority on these and other actions to improve the management of this Department and to obtain the highest possible program return on the resources in the HHS budget.

As you review the details of this budget, I hope that you will reach the conclusion that it merits your support.

Mr. Chairman, before proceeding to questions, I would like to have two members of my staff join me at the witness table.

Senator WEICKER. Please.

Secretary HECKLER. Thank you. The Assistant Secretary for Legislation, Mr. Thomas Donnelly, and the Assistant Secretary for Management and Budget, Mr. Dale Sopper.

You can see why I need an assistant for budgetary purposes. You can see our budget book; he carries it. He has a stature similar to yours, which is more adequate to that task than mine.

Senator WEICKER. Well, you have a building downtown geared to housing employees, and I not only have that budget but the Department of Education. I have one room down here to house my staff, so you just enjoy a slight advantage at this point of the discussion.

Now, the question is whether or not we have the capacity to match wits, if you will, and I hope we will try to arrive at a budget acceptable to all.

Secretary HECKLER. Mr. Chairman, you have control over the billions. That is by far the superior position.

Senator WEICKER. No; who has the votes controls. I have not been alerted to the fact that my philosophical disposition enjoys the majority of the votes in the Congress of the United States.

First of all, let me just make something clear because I don't want the wrong impression to be given as to the statement that was made about the $289 billion budget projections being 34 percent of the total in fiscal year 1984, $48 billion more than the defense budget.

They say here on the Appropriations Committee if the various moneys are allocated, it is my understanding—and the counsel can correct me—that my entire budgetary responsibility is about $100 billion and that of the Defense Subcommittee is about $208 billion.

So I don't want the impression to be given that this part of the budget is more than defense. It is slightly less than defense. What you are doing is putting the social security funds in there, over which we really have no control here, except as the law was changed most recently, but that certainly does not come under the discretion of this subcommittee or the Appropriations Committee so far as those funds are concerned.

I also would like to point out, just as a matter of history, that the charts that were shown starting in 1950, in effect right after World War II, indicated that rapid growth took place in that period of 20 years, and I don't consider that to be unusual in that we were for the first time facing the internal problems existing in this country rather than piling all our money into defense.

I am not saying we are not about ready to go back the other way again, but the fact is that in 1950 neither the health care opportunity, the educational opportunity, the housing opportunities—right down the list—were available to the great numbers of our citizens. That is the case today.

This was the natural thing for a Government at peace to do, and it has been done. I don't find anything unusual about the rapid increase unless there was some occasion why we should not be spending money domestically.

Let me leave that, and get to the questions that relate to your budget.

HEALTH INSURANCE FOR THE UNEMPLOYED

The President's Commission on Ethical Problems in Medicine in its recent report indicated that 22 to 25 million Americans have no health insurance. It seems clear that many of these individuals are from the ranks of the jobless, and I would like, first of all, to have an indication from you as to how you view this current situation, what you are planning to recommend to the Congress to address this situation, particularly as it affects the jobless.

Secretary HECKLER. Well, of course, I have a great sense of compassion for the jobless in this society, and I think their health care needs are a very pressing social concern. I have been in discussions and consultations with Senator Durenberger, as well as Senator Dole, members of the Finance Committee, and with David Stockman, in an attempt to find a means of dealing with the temporary jobless and the problems of health care for them during this interim period.

There are various areas of discussions going on in the executive branch. We expect Senator Durenberger here in the Senate to hold hearings on this subject very shortly. We are working jointly to try to develop some criteria for a plan which would satisfy the current problem as well as not create a new entitlement program which would be an endless strain on the budget. There is a need to develop a policy that meets the specific dimensions of the situation we face today, and that is under ongoing discussion, a very active, intensive discussion.

Senator WEICKER. I would like to have an idea of a time view of when you plan to have something in place.

Secretary HECKLER. Well, we had hoped to be able to present testimony of a concrete nature before Senator Durenberger's committee and this subcommittee at the same time. The consultations are taking place on a daily basis with representatives of the Senate staff that I mentioned and David Stockman's office and my office.

My Assistant Secretary for Planning and Evaluation is dealing with this issue and is meeting on a daily basis. As I said before, we were looking forward to a concrete proposal being drafted in the next few weeks, hopefully by the end of recess, but——

Senator WEICKER. The Presidential Commission concluded that the ultimate responsibility for assuring equitable access to health care rests with the Federal Government.

Now, I can appreciate the consultations with staff and Senators and hearings and all the rest of it. The fact is that it does little good to somebody that is not in a position to avail themselves of health care at this juncture.

I have recently seen on television several different programs, I think covering all the networks, maybe even some of the independents, that highlight the fact that the indigents are not getting health care.

Mainly, they focus on the fact that the hospitals are most anxious—and many of which are privately owned—are most anxious to take on those patients that can pay and have health insurance. We have 22 to 25 million Americans that don't have that kind of insurance, and in terms of being able to pay, obviously that problem is exacerbated by their being out of work.

I think that this is something that should be addressed now and not later. Maybe there might be a long-range problem here, too, and I am sure there is, but again, I repeat, the situation is urgent, and I am trying to find out whether or not the administration plans to have something on the books that can be utilized within the next several weeks, or whether we are just talking about really the beginning of a long constitutional process which might end up in a year's time having some assistance for some of these people.

What happens to the people during the next few years that don't have that insurance or that access to health care?

Secretary HECKLER. I can assure you that there is a sense of urgency about the need to address this problem. As a matter of fact, the Departments of the Treasury and Labor are also participating in the consultations on the drafting of a new proposal.

One of the reasons for creation of this task force, combining both the executive and the legislative branches of Government, was to be able to present a proposal to the Congress that had Executive support, and, therefore, could be passed with the speed that this particular problem actually deserves. There is a very serious ongoing process, and it is, I think, going to produce a proposal which we will offer to the Congress as one that has the support of the President. Hopefully, this could be passed not only in this session of the Congress, but we would hope, before the end of the summer.

Senator WEICKER. Have you had any cost estimates on what it is you are proposing?

Secretary HECKLER. At this point I have not, Mr. Chairman, but I would be glad to provide for the record any information that we might have.

Of course, the discussions are tentative, and there are exchanges of views and exchanges of estimates, so that there is nothing that is sufficiently solid to really give us a good feeling for the cost of the program.

Senator WEICKER. The administration has proposed reducing the developmental disabilities program overall by 32 percent. The basic State grant portion of this program would be cut by 43 percent. With increased pressures on the States to pick up the slack to serve the 4 million people who have developmental disabilities, how can the States be expected to effectively fulfill their Developmental Disability Act requirements with such drastically reduced funds?

Secretary HECKLER. Well, as you know, Mr. Chairman, the purpose of the developmental disabilities core program was to coordinate and focus on all of the sources of assistance available to those who fall within that category, the severely disabled, and not to directly fund programs that would deliver direct service to those who are developmentally disabled. The administration believes that the core funding for the State developmental disabilities councils has been preserved under the new budget request and that these councils are going to be a force in the States to reach out and to fund the direct service program.

I would like to say, also, Mr. Chairman, that we feel it is the responsibility of the councils to really search out all means of assistance. This was part of their mandate when they were established, and I think they are terribly important.

One of their key roles is to identify funding sources that are available in other programs, and they will be able to continue to do so, despite the fact that there is a cut in funding in the program. The councils themselves will be preserved and they will continue their mandate to look for other sources of funding in the private sector as well as in the Federal Government, but at a lower administrative cost.

Senator WEICKER. Again, to make clear to those who are not familiar with this program what we are talking about are the most severely disabled of our citizenry, and I just don't see, Madame Secretary, where it is fair in any manner, shape or form to inhibit the assistance going to these people in the hope that something might be worked out either at the State level or private enterprise, volunteers, or whatever. The people served in developmental disabilities are not served in vocational rehabilitation or special education.

You are cutting both the Federal funding and the basic State grants, and the result of all this is a sizeable diminution in the population served by developmental disabilities. Is that a fact? Do we know that?

Because all of a sudden, there are many fewer people served by developmental disabilities? Is that maybe a reason for this?

Staff tells me that it is not. So what do you think is going to happen to these people?

Secretary HECKLER. One of the things the Department is doing to better serve the population is implementing section 2176 of the 1981 Omnibus Reconciliation Act which authorizes the Secretary to waive certain sections of the medicaid statute in order to expand coverage of home- and community-based services as an alternative to institutionalization. This provision really allows for greater flexibility at the State level in designating their programs.

In fact, HCFA, one of the agencies of my Department, has approved 38 waiver requests from 31 States to date, and there are 19 requests pending in the Department. Many of these waivers are specifically targeted to the mentally retarded population and provide for rehabilitation, adult day care, case management, personal care, and other services.

I would also like to say that in terms of the intermediate care facilities for the mentally retarded we expect Federal outlays of $2.2 billion in 1983, to increase to $2.4 billion in 1984, for these facilities.

We also feel that the continuing funding by States of community-based services through the maternal and child health block grant, total estimated Federal outlays of $112 million in 1984, will help to address the problem.

But, frankly, one of the best opportunities will be the home- and community-based service waivers which allow States to develop more innovative approaches to meeting needs of the disabled, and that is one of the approaches that the administration has promoted.

Senator WEICKER. Well, several comments. First of all, the granting of waivers to the States, all that does is relieve the States of their obligation to serve the developmentally disabled. That doesn't do anything for the developmentally disabled, and that to me totally avoids the thrust of this question, as you know.

How is this going to affect the individual in that bed or in that wheelchair, or whatever? How is this reduced budget going to help that person?

Answer: We are going to waive the legal requirements imposed on the States to help that person. Great. That might save the State treasury some money. I am not going to argue that. It sure as heck is not going to help that individual.

Secretary HECKLER. The idea, of course——

Senator WEICKER. These requirements were placed on the States because they were not giving that assistance to these people. I don't understand how that resolves the problem.

I keep on hearing the word "innovation." I think that is probably due to the thrust of the Federal Government.

There has been much innovation in this area, as anywhere else, to the point where we are asserting a leadership role in making these people whole and giving them a part in our life as a nation.

Now it is not as if these people have been dragging their feet. I am not going to get into this much further, Madame Secretary, but this is a clear area where some moneys are being saved at a terrible human cost.

Secretary HECKLER. Well, Mr. Chairman, I believe that the flexibility which the waiver permits will help States to develop alternative means of serving the disabled. In fact, the program that has been reduced, the DD councils, is a program of State grants which is used to coordinate services; these funds do not go to individuals. The programs that directly benefit the individuals are SSI, OASDI, maternal and child health block grants, and medicaid.

The idea of the waiver is to liberalize the strict and very rigid requirements on availability of medicaid funding for home and community-based service and allow States better service to the disabled.

Senator WEICKER. Counsel points out to me that the maternal and child health care program was not meant to be a DD program.

Now, I think you people are packing a great deal in here to go ahead and make up for the shortfall in funds.

Secretary HECKLER. But the DD program is not the primary source of direct funds to individuals under any circumstances. The DD program provides grants to State councils that are designed to coordinate and provide a State focus for all of the available resources for the disabled. And under those circumstances, the councils work to pinpoint and to identify new sources of funding for people.

Under the waiver program, we in the Department feel that the disabled will be better served by being able to stay at home rather than be institutionalized. By allowing the medicaid regulations to be relaxed and encouraging flexibility, new approaches to care can be developed for the disabled, and Federal funding will be available for these services which were not fundable prior to 1981.

The maternal and child health block grant was not designed specifically for the disabled—there isn't a single program that was designed just for the disabled except for disability insurance programs. In fact, however, the crippled children services program was put specifically into the maternal and child health program because it was felt that this was a program that would relate to the disabled in that category.

And staff points out, Mr. Chairman, that there is good evidence that the States are continuing the same proportionate level of funding for crippled children's activities under the MCH block, and that they are level funding it in 1983. The States are continuing to deal with that particular problem and with that particular program.

Now, I would say, Mr. Chairman, we both share a concern for the disabled. The question is how are we going to meet the needs of all of these deserving constituents.

Senator WEICKER. Let me say one thing right now. I hear that statement coming across again and again by the administration as it cuts the budget.

To me, concern in this area definitely relates to dollars. Now you don't get it on the cheap, Peggy, and you know that just as well as I do, not in this area of cost.

Secretary HECKLER. You have to make the dollars stretch, Mr. Chairman.

Senator WEICKER. A $24,674,000 budget request just doesn't even meet the minimum funding required by law to cover the statutory State allocation formula.

What is the minimum amount currently required by law to meet the prescribed allocation formula?

Secretary HECKLER. According to my information, funding of $32.1 million is necessary to meet the minimum basic State grant allotments currently required by the statute.

Senator WEICKER. Why are we requesting only $24 million?

Secretary HECKLER. The budget request for $24.7 million includes special appropriations language to authorize funding below the existing minimums. Of course, we realize the limitations of that language. It could be subject to a point of order and the very point that you have raised.

LEGISLATIVE REQUESTS IN APPROPRIATIONS LANGUAGE

Senator WEICKER. It is subject to a point of order right now. So I will save you all the trouble. I am not going into the U.S. Senate with any legislative changes being achieved through the appropriations process by the administration.

I have said this to every single person that has come before this committee. If you people want to do it, you do it right there on top of the table, according to the way the system is set up.

And as far as I am concerned, neither is this proper budgetary procedure—in the sense that what you are doing is to give me a budget based on your speculations to what you can achieve legislatively rather than dealing with the budget as the law is now written, and I can assure you that this will not be done through the work of this subcommittee; indeed, the Appropriations Committee will not legislate on an appropriations bill, and, I can also assure you on this point, even if you bring it up at the regular course of business we will fight it there.

To those of your colleagues that appear here with you, Madame Secretary, I would only suggest that your budget be prepared on the basis of what is the law rather than what you hope the law is going to be.

I mean for conservatives, which you all like to think of yourselves, that is a hell of a way to prepare a budget. I have never done one that way myself—on the basis of what could be. I prepare a budget on the basis of what is. And, indeed, if I am going to speculate, I speculate on the larger amount for the greater liability.

Am I correct? Is this correct procedure, fiscal procedure, according to good conservative practice—and I might add also for good fiscal practice—regardless of whether it is practiced by conservatives or liberals or anybody else?

But to achieve savings on a speculation—never mind to achieve savings at the expense of the disabled—I don't understand that, just as a matter of practice.

Secretary HECKLER. Mr. Chairman, every Department has submitted to the appropriate appropriations subcommittees budgets based on changes in law which will be requested as changes in the appropriations bills and, hopefully, changed in the authorizing committees as well.

That is a Government-wide policy. Of course, it is your function to determine your response to it.

Senator WEICKER. It is the administration's policy. It is not Government policy. It is administration's policy that they are trying to use the appropriations process to achieve legislative changes.

Now, I will tell you how bleak the outlook is. Am I not head of the subcommittee on the authorizing side that would hear this change if it were presented? So there you have it. [Laughter.]

That sums it all up. You know, you lose here, you lose there.

So let's get to the figure that is required by law, which is some $32 million plus.

Secretary HECKLER. This is OMB policy, Mr. Chairman.

LEGISLATIVE PROPOSALS

Senator WEICKER. To follow up on this point of legislative savings, the Department's budget seems to be filled with proposals to save money through new legislation, which you ask this committee to approve. The budget asks to eliminate the health planning program, cap the health professions guaranteed loan program below the authorized level, put a limit on national health service core loans, authorize the Secretary of HHS to use her discretion to determine the allocation formula to be used under the low income energy assistance program, authorize mandatory copayments by medicaid beneficiaries in place of the optional copayments authorized just last year and reduce AFDC benefits by $722 million through a series of proposed changes to the Social Security Act.

Have you submitted these and other legislative proposals to the Senate Labor and Human Resources and Finance Committees, which are the proper places for them to go, and what reaction have you gotten?

Secretary HECKLER. Mr. Chairman, most of the major legislative changes we are proposing have been transmitted to the Congress.

These include the Public Health Service Act amendments, maternal and child health block grant amendments, medicare and medicaid amendments, including prospective payment, medicare restructuring and vouchers, and other proposed changes, except for the low income energy assistance program amendments which are at the Executive Office of Management and Budget at this moment.

The proposals that I have suggested are in the Congress. The others are at the Office of Management and Budget.

Senator WEICKER. Well, I wonder if you might help me do my job in this committee in assuming how much more money would we be required to appropriate if the Congress does not enact your so-called legislative savings?

Secretary HECKLER. $6.8 billion would be saved in this budget if the legislative changes proposed by the administration are actually translated into law.

Senator WEICKER. And if they are not, will require an additional $6.8 billion dollars, is that correct?

Secretary HECKLER. A portion of that is trust fund changes.

We are dealing with a budget that is at $289 billion, and of course, as you pointed out yourself, this subcommittee does not deal with the total budget for the Department of HHS. I spoke to the total budget. The area that you would have authority over is $691.4 million.

Senator WEICKER. That is a lot.

Secretary HECKLER. It is a very important area of the budget, I would say, in terms of the impact.

Senator WEICKER. I would appreciate it if you would give us for the record a breakdown of the $691 million, so that we can do our work as I believe it should be done, which is based on current law, and gives the hardest picture rather than potentially the easiest.

Secretary HECKLER. We will be happy to do that.

[The information follows:]

1984 legislative savings proposals affecting HHS appropriated entitlement programs

	1984
Medicaid:	
Mandatory copayments	−$249,000,000
Assignment of rights	−6,000,000
Crossover claims	−1,000,000
Impact of medicare proposals	+49,000,000
Impact of AFDC proposals	−93,000,000
Subtotal, medicaid outlays	−300,000,000
Aid to families with dependent children:	
Include parents and siblings in filing unit (except SSI kids)	−131,000,000
Prorate shelter and utilities	−229,000,000
End benefits when youngest child turns 16	−22,000,000
Mandate workfare	−275,000,000
Prohibit payment when parent's absence is due to employment	−5,000,000
Permit States to require parents with children age 3–5 to work if child care is available	−3,000,000
Sanction someone who chooses not to work	−1,000,000
Mandate changes in State laws	−56,000,000
Subtotal, AFDC outlays	−722,000,000
Child support enforcement:	
Phase-in restructuring of financing and provide bonuses	−10,000,000
Supplemental security income:	
Six-month delay of COLA	−145,000,000
$30 additional income disregard	+530,000,000
OASDI offset for windfall benefits	−14,000,000
Other proposals	−30,000,000
Subtotal, SSI outlays	+341,000,000
Total	−691,000,000

TRANSFER OF HEALTH BLOCK GRANTS

Senator WEICKER. Your budget proposes to shift four health block grants—primary care and maternal and child health, preventive health, alcohol and drug abuse and mental health from their traditional agencies to the Office of the Assistant Secretary for Health, an office geared more to policy setting than grants administration.

The Department has proposed this sort of shift in the past, and Congress has done nothing about it. So now you are trying again.

I was wondering whether a hard run was going to be made at this or whether we should all save our time, because I can pretty much predict what the Congress is going to do and get on to other things.

Secretary HECKLER. Mr. Chairman, we are making this proposal again, and there are strong arguments for consolidating these programs.

The administration of the block grants in a single agency would save management costs. It would serve to streamline Federal administrative functions and achieve economies of scale.

It would provide a single Public Health Service office contact for the block grants.

There are management and economic reasons for the proposal, Mr. Chairman, and it is for these reasons that the administration is presenting the request for consolidation again.

Senator WEICKER. Your plan would involve—and I pose this as a question—your plan would involve the abolition of some 435 positions related to primary care and maternal and child health block grants; is that the correct amount?

Secretary HECKLER. Yes; that is correct, Mr. Chairman, because the consolidation of the administration would provide these savings. The idea behind this is the fact that the combination of the programs would be——

Senator WEICKER. Forty people?

Secretary HECKLER. Forty.

Senator WEICKER. How are 40 people going to go ahead and manage this?

Secretary HECKLER. Consolidation of several categorical programs into the primary care block grant would simplify grant procedures and transmission of the funds to States can be accomplished with a much smaller number of staff. It is a more simplified, consolidated, and efficient administration of the programs.

It would not change benefits to the recipients. The beneficiaries would receive the same amount.

Senator WEICKER. Well, it may and may not, depending on whether it——

Secretary HECKLER. Excuse me, Mr. Chairman, I would like to correct that. It is 20 per block grant. So a total of 80 persons would administer the block grants.

Senator WEICKER. How many are administering these programs now?

Secretary HECKLER. Mr. Chairman, the information that I have is that for the existing maternal and child health block grant, the prevention block grant, the alcohol, drug abuse and mental health block grant, these programs partly are administered by 20 people per block grant.

Now, in terms of the impact on employment——

Senator WEICKER. Where is your 435 positions you are abolishing coming from?

Secretary HECKLER. They represent staff now managing three categorical programs proposed for consolidation in the primary care block grant. The actual consolidation of other categorical programs into block grants has already occurred resulting in some management savings in these blocks.

NONDISCRIMINATION IN BLOCKS

Senator WEICKER. Let me move on to the next question which relates to this area. It has now been about 1½ years since passage of legislation authorizing the establishment of block grants.

The Congress clearly reaffirmed the national policy objective of ensuring nondiscrimination in Federal assistance programs by including specific civil rights language in most block grant titles in the Reconciliation Act.

My understanding of your preliminary draft of implementing rules fails to include prohibitions of discrimination. In addition, it appears to have instructed your program offices to use existing data, and they have been directed to—and I quote—"under no circumstances were they to contact the States for any data."

If the Department is not planning to contact the States to obtain data, how will it obtain data which is adequate? And when do you plan to have regulations on this matter firmed up? And will they contain adequate safeguards against discrimination?

Secretary HECKLER. Mr. Chairman, I can assure you that I intend to preserve safeguards against discrimination, and that is something that I would consider very important. In terms of the——

Senator WEICKER. Well, the preliminary draft doesn't have any.

Secretary HECKLER. I am sorry, I can't say that I have seen that preliminary draft. You are presenting new information to me.

Senator WEICKER. So I am perfectly satisfied if you will give me your assurance that you are going to make sure that whatever subsequent draft comes along is going to have that prohibition in there.

Secretary HECKLER. Oh, I have no intention of eliminating prohibitions against discrimination. I have not seen this particular document.

Senator WEICKER. When are the regulations going to be firmed up?

Secretary HECKLER. Mr. Chairman, the Office of Civil Rights in the Department is preparing the regulations. We do not have the specific information on this, and we would be glad to provide it for the record.

Senator WEICKER. It is my understanding the social services block grant does not contain such language in the Reconciliation Act.

Secretary HECKLER. I am informed that the proposed changes to the block grants formulas do include language to prohibit discrimination of all types and that the language of our proposal has already met your objections.

Senator WEICKER. Let's just make sure it is in there.

FUNDING FOR THE NATIONAL INSTITUTES OF HEALTH

Senator WEICKER. One of the most important enterprises under your jurisdiction is the National Institutes of Health. NIH is the most significant institution of its kind in the world, representing all of our hopes for conquering cancer, heart disease, other afflictions that bring pain, misery, and death to so many people each year.

We know from your statement the administration decided to support 5,000 new and competing research grants in fiscal year 1984 rather than the 3,676 shown in your budget.

But you propose to do so without increasing the overall dollar level in the budget. How much will this approach cost other important NIH initiatives such as continuation grants, clinical trials, training, research centers, et cetera?

Secretary HECKLER. Mr. Chairman, our requests include an increase of $73 million. We will have to find $140 million from the other activities and programs within the total of $4.1 billion in the NIH budget in order to accommodate 5,000 new and competing grants.

The new and competing grants are really the lifeblood of basic research; and this is such a fundamental function of the NIH that the 5,000——

Senator WEICKER. Again, this is the sleight of hand which I don't really think is a credit to the administration or anyone involved. In this committee we won't get involved.

The speech is fine. It says we are going to go ahead, and your speech supports 5,000 rather than 3,600 some odd research grants.

So a person out there reads that, and they figure, "Oh, gee, everything is all right; the administration has gotten the message."

Not so. There is no additional money being proposed to accomplish this. It is going to come out of some other programs which also have great value, and it is not a matter that was given thought.

The administration's initial budget came up on January 31. Now here it is some 2 months later, almost 3 months later, we have this switch. Now we are going to go ahead and pay for it, some $140 million plus, out of other programs all within NIH.

And I don't understand that. I would far rather that—if the administration feels committed to this area—they also have to have some money to pay for it.

Secretary HECKLER. Mr. Chairman, we don't have the money to pay for everything we would like to fund. You know, we are in a period of constraints. These are difficult times in the sense that Federal funding, if it is going to be curtailed, is going to have to be allocated to the right priorities.

The choices are hard. They are very difficult. I think that the administration is right in funding the 5,000 new and competing grants.

This meets the major need of NIH to constantly search for new initiatives, new ideas. The funding does require a difficult redistribution, and at the moment we are in consultation with the Director of NIH and departmental officials for their best advice on where the cuts are going to be made.

I think, in meeting the fundamental research needs of NIH, we are putting our priorities in the right place, and I can't say that funding everything wouldn't be desirable, but there are limits. This is one of our very difficult but pressing needs.

Senator WEICKER. But you made your choice. You made your choice when you sent us your budget. Obviously, there has been some compiaints that have arisen over the past several months over where it is you cut. And we are responding to that complaint.

Secretary HECKLER. Mr. Chairman?

Senator WEICKER. In responding to that complaint, what you are figuring is that we will hit at another area; hopefully, they will not have time to generate any sort of complaint and we are going to get away with it.

First of all, let me say this: The NIH hearings are next Tuesday and Wednesday before this committee, and I want a breakout then as to what it is you are going to go ahead and do in these other areas.

What I am saying is that it does take courage to go ahead and stand up, not just to ask for programs—the Congress is famous for that.

If you feel that this is a priority and obviously you do because you changed your budget request, why haven't you asked for the money to pay for it?

Now, I read the paper this morning, and at present, according to a report that I read, the administration is prepared to go ahead and drop $8 to $10 billion—$8 to $10 billion off of defense. You know, that is good news. It seems to me that certainly $140 million fits in the overall scheme of things.

It might be nice for a change, you know, if this Nation put its monetary priorities on the side of life. As I get older and my friends get older and I see a little bit more of the country every day in the position that I am in and I see somebody that has died of diseases, I get so damn frustrated. You know, we can't do everything in the world; why can't we just take care of the flesh and blood around us? This is where it all takes place, right here.

NIH RESEARCH ACHIEVEMENTS

Secretary HECKLER. We are making great gains in the NIH, and I am proud of their research. The President's proposed cut in defense is going to take place over the next 5 years, not in 1 year.

I think that the NIH breakthroughs are very encouraging. We just recently had the preliminary results of an NIH grant on Alzheimer's disease, and we find that there is reason to hope that memory loss can be reversed.

Senator WEICKER. Well, now, Peggy, let's not have the administration take credit for something that has been in the works for long before the administration got here.

Secretary HECKLER. The administration is funding these things.

Senator WEICKER. Now, you know as well as I know, the administration is not funding these things. This is the point I am trying to make.

The funding that was put in—in other words, the very breakthrough you are citing now—this happened years ago, and that is the problem with what you are doing with this budget. Nobody knows the terrible cost that is going to be paid in the out years.

You achieve a savings as far as the paperwork is concerned now. You know medical research as well, if not better than I do, Madame Secretary, and you know that it is the investments that are made now which have absolutely nothing to show, that are going to pay off 6, 7,

and 8 years from now. And hopefully, by that time everybody that is involved with this process, you see, will have tiptoed off the stage. But the ones who go ahead and suffer are the ones that will not be the beneficiaries of that research.

Now, regarding the $140 million—I will ask you three questions: Is it going to be taken out of clinical trials on diabetes? Is it going to be taken out of arthritis centers? Is it going to be taken out of continuation grants for cancer and for heart disease?

Now these are the areas where it is going to have to come from.

Secretary HECKLER. There are a number of difficult choices—you know, they are very difficult choices, but I would like to say that I think at times the administration does deserve a little credit. Indeed, in its pursuit of answers, funding the basic 5,000 research grants which Secretary Schweicker has requested is one such area.

Senator WEICKER. All right, and you say the administration deserves credit. Fine. You want credit. If you want the hosannas to ring, walk over to the Defense Subcommittee. The President deserves credit. But there is very little credit that is going to be passed out in this subcommittee.

In this field of Government endeavor under this administration now, if we want credit, fine. This costs money. There is nothing more expensive in the world than research, medical research.

Now, I just don't know how to deal with null dollars. Neither do you and neither does the President. We can have all the coordination in committees and staff meetings and all the rest; it cost bucks.

Regarding the cost of research and development to the Government, I might add just so that we might put it in the area that the President knows best—there is not one great medical pharmaceutical house in the United States of America that won't tell you that the biggest part of their budget is R&D, and the percentage that comes out of that insofar as new products are concerned is directly related to the dollars put into R&D.

Now we are no different. The Government is no different than they are.

Secretary HECKLER. That is why we are trying to put moneys into R&D, and that is why we are trying to continue to refurbish the pool of new researchers and new scientists so that at least we will continue to bring fresh blood and new thinking into the research area.

That is the point of having the 5,000 grants, because that is the number of grants that would continue to refresh the system.

Senator WEICKER. We will take a look at that, but again I repeat that I want that breakout by the next hearing, and it would be the inclination of the chairman, whether or not the committee goes along with you or not, that it would certainly be the inclination of the chairman to go ahead and grant your request for 5,000, but also to go ahead and tack on to that the funds necessary for 5,000 and not try to seek those funds out of other valuable research going on at NIH.

Secretary HECKLER. Mr. Chairman, we will provide our proposal in as much detail as possible for your next meeting.

COMMUNITY SERVICES BLOCK GRANT

Senator WEICKER. Your budget proposes abolishing the community services block grant which is currently funded at $373 million for fiscal year 1983, based on the premise that this program duplicates the social services block grant.

Then why, in light of the fact that the budget request is $548 million below existing appropriations for these two programs, what evidence is there that services to impoverished individuals currently provided by the community service block grant will not be adversely affected by consolidation with the social services block grants?

Secretary HECKLER. There is overlapping in the two programs, and that with the limited funds in the budget, again tough funding choices have to be made.

These decisions are really hinged on the establishment of priorities, and it was felt that the community services block grant was less essential than other service activities. In fact many of the programs included under the community services block grant will be funded under the social services block grant. So you have duplicate funding for many of the same programs.

It is also felt that having one centralized source of funds for the purpose of encouraging independence from public assistance will probably most effectively enable State and local governments to mobilize their resources and plan their service delivery assistance. This proposal would allow certain cap agencies that are performing very well to be funded by the State under the social services block grant.

It is a consolidation of funding under the social services block grant in an attempt to cut costs and prevent duplication.

Senator WEICKER. Now wait a minute. What you just said is that you are going to cut some services to impoverished individuals, at a $548 million cut.

Secretary HECKLER. There is an overlap of the two in terms of the coverage.

Senator WEICKER. Are you going to cut services to impoverished individuals?

Secretary HECKLER. I would hope not.

Senator WEICKER. You would hope not?

This $540 million is strictly administrative——

Secretary HECKLER. No; it is a block grant, Mr. Chairman. It is not an entitlement program. It does not go on the basis of entitlement statutory provisions funded from trust funds.

Senator WEICKER. I understand that, but I am saying even when you block grant, even when you push these two together, if I am not mistaken, it is $548 million below the total of the two.

Now I want to know if services to impoverished individuals will be cut back?

Secretary HECKLER. The funding is going to be reduced obviously, since you are going to have a lower figure, Mr. Chairman.

Senator WEICKER. Well, I know that the funding is going to be reduced. That is a matter of record. I am saying are services going to be reduced?

Secretary HECKLER. The States will allocate the funds that are available. It is a block grant now, and the question is how the States can use this allocation, what other resources do they have, and what other programs can they draw upon?

Yes; there are tough funding decisions here.

Senator WEICKER. No, no; the decisions might be tough, but the impact on the individual is tougher. They are the ones that suffer. We don't suffer with our decisions.

Secretary HECKLER. Well, the fact of the matter is that there are those who are not covered by the community services block grant, and there are those who are fortunately in a geographic area to be covered by the program. Others are not beneficiaries because they are not within the purview of the cap agency itself.

So the program has an uneven response, an uneven impact. The administration favors consolidation into the social services block grant.

Senator WEICKER. If you want to eliminate the community services block grant, why don't you propose repeal to the authorizing legislation?

Secretary HECKLER. We are proposing this, Mr. Chairman.

Senator WEICKER. So this is again speculative, is that correct?

Secretary HECKLER. Yes.

Senator WEICKER. You would not expect me to do it because that is up to the authorizing committee.

Secretary HECKLER. It is predicated upon an authorization change.

On the other hand, Mr. Chairman, it is a discretionary program. If there isn't an appropriation from this subcommittee, then that is a decision that can be made without legislation, because it is not an entitlement program.

LOW INCOME ENERGY FORMULA

Senator WEICKER. You're proposing appropriation bill language to determine an allocation formula for the low-income home-energy assistance funds among the States.

Can you tell us how you would distribute low-income home-energy assistance funds among the States if you had discretionary authority?

Secretary HECKLER. These funds will be distributed on the basis of heating degree days and climatic impact.

We have to take cognizance of the fact that States have the ability to transfer funds out of the program into other block grant programs, and while many States have transferred funds from the program, no State has transferred money into the low income energy assistance program.

In terms of a formula, Mr. Chairman, there are proposed formula changes in the Department that are coming up to me through the pipeline but have not come to my office at this point.

Senator WEICKER. You are proposing a cut of $686 million in low-income energy assistance. That's about a 33-percent cut.

Now, are we going to serve as many, more or less, persons in lower income energy assistance, or is this just the way of the administration for verifying voluntarism?

Secretary HECKLER. Not quite, Mr. Chairman. But we have surveyed this program, and 28 States intend to transfer out approximately $93 million. In 1981–82, 33 States transferred out of the block grant approximately $100 million and no State has indicated it wants to transfer funds into this energy block grant.

Now, second, States also carried over from their prior year funding $170 million of unobligated fiscal year 1982 funds into 1983.

States do have the option of transferring funds from the social services and community services block grants. No States have exercised that option. And so, obviously, since the transfer out has occurred in so many States, there is the feeling that these funds have not been the highest priority with the States, and I think we should fund the States that have the greatest energy needs.

Of course, we do have the benefit of lower heating costs as well, so that's a factor, Mr. Chairman.

Senator WEICKER. You also have the benefit of more poor people, and you have more people out of work, and you have less availability of funds at the State level.

In fiscal 1983, Congress pushed funding to $1.975 billion. The authorized level was $1.875 billion. Were you one of those, Madam Secretary, voting for increase in the low-income energy assistance as a Congresswoman from Massachusetts?

Secretary HECKLER. Mr. Chairman, my prior life imposed a different perspective. But I have to say this, I am sympathetic to the program, as you know; and I could not come from a northeastern State without feeling that.

At the same time, when States do transfer out, consistently, large funds from that program, and do not, themselves, consider it a priority and you consider the fact of lower costs for energy, there are factors that have to be taken into account in dealing with this.

I am also reminded by my associates that in the AFDC program, there is a provision for energy costs and that the low income energy program was not intended to cover 100 percent of the need for 100 percent of the people. The fact of the matter is that it is a supplementary program.

We are, in the Department, developing a proposed formula to submit to you which we hope will cover the real needs of those who are deserving and feel the pinch. We will provide a formula for you, Mr. Chairman, in the near future——

Senator WEICKER. But the formula is funded some $686 million below current levels.

Secretary HECKLER [continuing]. That is a budget proposal.

Senator WEICKER. Well, why don't we take a look at this, for the record, on a State-by-State basis, to which the proposal——

Secretary HECKLER. We'd be happy to provide the subcommittee with a State-by-State allocation table and explanation as soon as the formula is finalized.

[CLERK'S NOTE.—At the time of printing, the allocation table had not been received by the subcommittee.]

Secretary HECKLER. Mr. Chairman, we're dealing with a $289 billion cost for this Department, and we're trying to find ways to cut. I feel, as a former Member of Congress, and know you, as a Senator today and former colleague of mine in the House, unless we find a way to deal with the vast entitlement expenditures of this Department, we will look at a shrinking dollar availability for some very important needs in discretionary programs.

Obviously, hard choices have to be made. We have to find ways to be more effective, to do more with less. There are so many untouchable funding areas of this Department that it's only in the discretionary area that changes can be made and, hopefully, innovation and flexibility can be encouraged. We need to provide the same innovation, flexibility, and cost savings in the larger entitlement area to stretch the dollar even further in order to do more in the discretionary area.

Senator WEICKER. Well, you know I was always taught that if I was a witness not to start speaking for any more than what I was asked. If you want to raise the subject, I'll be glad to start discussing it.

But in your budget you are asking for reductions of—let me just add them up. I'm now looking where it says to eliminate community service grants, elimination of work incentives, health resources administration, refugee assistance programs, nutrition for the aged, and developmental disability: These are the big cuts in your budget. And they add up to roughly $1 billion, and then that will make it $1.4 and $1.5—$1.6 billion in cuts, $1.6 billion. That is rough.

The President today is reducing $8 to $10 billion from defense. He can go ahead and take care of that just like that. Why, that's nothing. This matched up against that and we could have everything restored to where it ought to be. But what I object to is balancing the Federal budget on the backs of the weakest elements of our society. I object to that.

You used to object to that.

Secretary HECKLER. Mr. Chairman, I have nothing to do with any other budget except this one.

Senator WEICKER. I would suggest, Madam Secretary, we restrict our conversation to that. And once you go afield from that, you are fair game.

Secretary HECKLER. All right. Fair enough, Mr. Chairman.

Senator WEICKER. And it's not a very fair picture out there, once we go outside this budget. It's difficult enough within this, but compared to defense it is a travesty.

The Nation has become aware of the increasing number of persons afflicted with acquired immune deficiency syndrome—AIDS—which carries a very high mortality rate. And I understand that as of March of this year, there are 1,112 victims and 418 deaths throughout the country.

ACQUIRED IMMUNE DEFICIENCY SYNDROME

We received, on March 22, a letter from Dr. Wyngaarden, head of the National Institutes of Health, indicating he expected the total public health service expenditures on AIDS in fiscal 1983 would be $10.1 million and then $9.3 million in fiscal 1984.

That doesn't seem quite adequate for the task, really. You might have another view on that. Would you like to express whatever your points are to the committee?

Secretary HECKLER. Mr. Chairman, this is a very serious problem that the Department is anxiously and aggressively seeking to resolve. It is a truly tragic situation in which the fatality rate is so high that it is a—well, it is a matter of the greatest urgency. The Department is applying all due speed and available resources and research to try to deal with the growth of this disease as well as the prevention of it.

No dollars are being spared and the best minds are devoting their time and their energy to the resolution of this. Tomorrow, my Assistant Secretary for Health will hold a conference and a workshop at the Department; in fact, today and tomorrow. The Centers for Disease Control is conducting a number of investigative studies of risk factors.

NIH is focusing its full research resources on projects and clinical trials related to AIDS diagnosis and screening and testing patients with hemophilia to develop data relating to the immune system.

FDA is studying blood-transfusion techniques for ways to eliminate risk of infection, especially for those with hemophilia.

The fact is, Mr. Chairman, CDC is devoting $4.2 million, NIH is devoting $12.5, and FDA is devoting $0.4 million for a total of $17.1 million. This is still a terribly serious problem, and I have to say, from the attitudes expressed in the Department, that all due speed and commitment is being advanced in addressing the situation. We're doing everything possible. The fatality rate is absolutely frightening.

Senator WEICKER. Would you expect, before the committee takes final action on the appropriations, to once again consult with NIH should there be a change indicated in this particular request?

Secretary HECKLER. I would be very happy to do so. I am in constant contact with CDC and NIH as well as Dr. Brandt on the subject.

HEALTH PROFESSIONS EDUCATION

Senator WEICKER. One of the most important activities under your jurisdiction is the health professions training programs designed to assure the Nation an adequate supply of health professionals as well as bringing their services to medically underserved areas.

How do you view yours and the Department's roles in the health professions field, to continue to develop an assured supply of training

to individuals? Or do you feel that this program ought to be eliminated?

Secretary HECKLER. We believe in the continuation of the program, Mr. Chairman. At the same time, the current statistics and information currently available indicate that, in some areas, there is an adequate supply of health professionals.

Our present budget request is for $116 million. The priority concerns within the $116 million include: Enhancing the distribution of health professionals to provide care to remote and underserved areas which include: Primary care training, at $43 million, area health education centers, at $15 million, and physician assistants, at $5 million. A second priority is encouraging minorities to choose health profession careers. The programs include: disadvantaged assistance at $18 million, and financial distress, at $6 million. A third concern is improving the utilization and distribution of nurses. In this case we have advanced training at $1 million, nurse practitioner support at $6 million, and special projects at $6 million. A final objective is preparing the health professionals to be more prevention oriented and meet the needs of an older population. The budget contains preventive medicine residencies at $1 million and special education initiatives at $7 million.

The funding request is for $116 million.

Senator WEICKER. I have your 1984 budget, reducing funding by about 32 percent.

Is that not correct?

Secretary HECKLER. A $29 million reduction in funding.

Senator WEICKER. I have a reduction of about $60 million.

Secretary HECKLER. It goes from $143 to $116 million. Mr. Chairman, I believe that there is a $29 million payment which is a one-time payment; so, that might be excluded. I can check if that is the $29 million for the record.

Senator WEICKER. So, what is the actual percentage? What is the dollar percentage——

Secretary HECKLER. I will provide the actual decrease for the record.

Senator WEICKER. $143——

Secretary HECKLER. To $116.

Senator WEICKER [continuing]. To $116.

That's a pretty healthy cut for something you believe in.

[The information follows:]

Health professions education

1983	$172,000,000
1984	$116.500,000
Change 1983 to 1984:	
Amount	−$55,500,000
Percentage	−32

PROBLEMS FACING NURSING PROFESSION

Secretary HECKLER. I believe in all of these programs; that is the difficulty.

The question, in part, is one of supply. For example, there is—our data indicate that the nursing shortage that we experienced earlier is not a current problem and that supply is adequate. However, there are other problems in the nursing field, such as providing specialized services, and, indeed, having nurses who are competent and trained come back into the practice. That isn't an area to be covered by the health professions budget policy.

Senator WEICKER. Well, again, here you raise something with the nurses; you propose to cut the nurses training program by some $35 million in fiscal 1984, compared to fiscal 1983, $48 to $13 million.

Now, the Institute of Medicine indicates that the nurse supply and demand would be a reasonable balance during the decade, but it would be very unpredictable beyond that point in time. And we get right back to the matter I raised earlier, that the dollars spent on nurse training now are going to impact into the next decade.

So, it is easy to say that things are going to balance now; therefore, we can make this dollar savings. But you could have a terrible imbalance in the next decade. And there is no way you could make up for that imbalance, because, obviously, the die is cast and there is no way you can compress nurses' training into 1 day, it's going to take its normal course of years. So, there is the difficulty.

Secretary H[illegible]ER. Well, one of the other difficulties, Mr. Chairman, is the fact th[illegible]e nursing profession faces other problems, such as: inadequate pay, poor working conditions, lack of professional job recognition, opportunities for advancement, and insufficient numbers of nurses with specialized skills.

The fact is that this program is not capable of meeting these other weaknesses in the area of nursing. We do have trained nurses, and I do agree that we will need them for the future, certainly; but they—the nursing profession, itself, is haunted by other difficulties that the program was never designed to address and really are within the purview of the hospital system or the medical system itself.

One of the areas that we do see for alleviation of this problem is targeting the assistance that we do provide to training institutions and hospitals with a view toward developing better means of addressing the issues of nursing such as the utilization and distribution. However, some of the problems that plague the nursing field are very difficult and not really related to Federal budgetary problems or policies.

DOLLAR IMPACT OF LEGISLATIVE CHANGES

Senator WEICKER. You'll forgive me for a minute. I want to go back to something I covered earlier.

I remember asking you the question: "If Congress doesn't go along with your so-called legislative savings, what do we have in the way of additional moneys which would be tacked onto your budget?" And you gave me the response: "$691.4 million."

Now, all of a sudden, I'm thinking, low-income energy assistance alone is $686 million.

Secretary HECKLER. Sir, this is in the legislative changes, not the amount of appropriations. In other words——

Senator WEICKER. You are asking for legislative change in low-income energy assistance.

Secretary HECKLER. It is a discretionary program. The formula change is a legislative change. It is not a funding change. The funding is within your purview.

Senator WEICKER. I understand.

Under present law she is mandated, am I not correct, to allocate the money in a certain way as appropriated?

Ms. INGRAM. That's right.

Senator WEICKER. If the appropriation is not cut, it has to be allocated in a certain way. Under discretionary you can come at it both ways, both through the appropriating process and the discretionary sector.

All I am saying is I want to make very certain, in the sense of proper fiscal practice, that when you come up with these figures for the committee that you indicate in there the dollar equivalent for every single legislative change that you have asked for and give the worst case scenario to this committee.

Secretary HECKLER. We will provide you with that data without prejudice, Mr. Chairman, and will be glad to provide that for the record.

[The information follows:]

AMOUNTS IN THE BUDGET DEPENDENT ON PROPOSED LEGISLATION

The only legislative savings proposals included in the HHS fiscal year 1984 budget are those that affect the entitlement programs. These savings total $0.7 billion and include the proposals I have identified earlier which affect aid to families with dependent children, child support enforcement, supplemental security income, and medicaid.

In addition, our budget assumes enactment of some other legislative changes, but these would not save money. These include:

Expiring authorizing legislation.—$2.8 billion is dependent on extension of existing authorizing legislation which expires at the end of fiscal year 1983. This is principally for NIH and ADAMHA research ($2.3 billion) and the entire Office of Refugee Resettlement ($0.5 billion).

Transfers.—Three programs totaling ($0.45 billion are proposed for transfer to HHS. These are: USDA's child care feeding program ($76 million); USDA's elderly feeding program ($100 million); Department of Labor community services employment program ($277 million).

Primary care block grant.—A portion $0.165 billion) of the primary care block grant request of $0.460 billion represents our proposal to consolidate the family planning, migrant health and black lung clinic programs into that block grant.

I would reemphasize that the funding request for the low-income energy assistance program is not dependent upon our proposal to revise the formula—these are two separate issues.

FAMILY PLANNING REGULATIONS

Senator WEICKER. In January, shortly before you took office, the Office of Management and Budget cleared the proposed regulations which required family planning clinics that received Federal funding to notify

parents of a teenage girl if a prescription for a contraceptive was requested. As a Member of Congress, you opposed those regulations.

As Secretary, what is your view of the regulation?

Secretary HECKLER. Mr. Chairman, the regulations are presently the subject of a court order and are not being enforced by the Department.

I can see the arguments on both sides. This is the policy of the administration and I support it. The regulations, however, are not being enforced.

Senator WEICKER. Do you plan to appeal the ruling by a Federal judge in New York which delays the administration's regulation?

Secretary HECKLER. Yes; it already is under appeal.

Senator WEICKER. And will your Department or the Department of Justice bear the cost of sending these regulations through court actions?

Secretary HECKLER. The Department of Justice will.

Senator WEICKER. At the end of fiscal year 1982, the adolescent family life program received a $9.3 million supplemental appropriation, and with these funds were awarded 50 demonstration grants and 12 research grants.

How do you respond to charges that the awards went to only one minority applicant and bypassed many inner-city areas with problems of unwed mothers particularly acute?

Secretary HECKLER. Mr. Chairman, I will have to say that I am not familiar with that. I will have to provide that information.

Senator WEICKER. I have a series of questions on this that you may respond to later.

Secretary HECKLER. I'd be delighted to.

Senator WEICKER. Madam Secretary, I know of your very long and illustrious career as Congresswoman when you dedicated yourself to the needs of the weakest elements of our society. And I realize that it is a difficult task to defend this kind of a budget.

CLOSING REMARKS

I might add that, knowing your personal beliefs and your personal record and trying to see you equate that with your position as Secretary you look somewhat like a pretzel at this stage of the game. But I look upon you as an advocate for all that you have stood for over the years.

There is absolutely no getting around the fact that these areas are costly. On the other hand, whether it is the retarded, whether it is the disabled, whether it is the diseased, whether it is the ignorant, whether it is those that are suffering from malnutrition, the return is enormous in human terms and also in financial terms, as we have discovered. And I only hope that all these and more will have your advocacy.

I think the administration has shortchanged them. Maybe there are others that have been shortchanged. We aren't here to argue that point; these people have been. And even if there is only one out there, it is not a matter of politics or numbers at the polls, it's a matter of what the spirit of this Nation is all about. And here is where we find our greatness, in this budget, not the other one. Not the other one.

Secretary HECKLER. Mr. Chairman, I would like to assure you that my concerns and commitment to people are as great or greater than they have ever been. I find myself in a unique role. At a time of limited resources, the challenge is greater, and the need is greater as well. I feel that I will carry to this Department the same commitment to people that I have always expressed and that you feel, yourself, a commitment that we shared.

Obviously, I am going to translate those concerns within the limitations of this budget into every real gain that I can make possible for the people who are the constituents of this Department.

I really feel that the President has as much concern for those in need as I do. I feel that as he looks at the budget and as I look at it, we have to deal with so many restraints—we deal with inflation, we deal with the economy, we deal with the total picture of what is best for this society and how to meet the needs of people.

And I want to assure you of one thing, I will always be a "heckler" for the things I believe in, Mr. Chairman, and as my role develops, I intend to pursue those causes that I think represent and meet the needs of the people whom we all serve in our different capacities.

PREPARED STATEMENT AND SUBMITTED QUESTIONS

Senator WEICKER. Thank you very much, Madam Secretary. I have further questions which I will submit for response to the record. We will also include your prepared statement.

Secretary HECKLER. We'll be happy to respond.

[The information follows:]

STATEMENT OF MARGARET M. HECKLER

I AM PLEASED TO APPEAR BEFORE YOU TODAY TO DISCUSS THE PRESIDENT'S FISCAL YEAR 1984 BUDGET PROPOSALS FOR THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS).

DURING MY SIXTEEN YEARS IN THE CONGRESS, I WAS ON YOUR SIDE OF THE TABLE ASKING THE QUESTIONS, AND EXPECTING PROMPT AND ACCURATE ANSWERS. NOW THAT I AM IN THE EXECUTIVE BRANCH, I INTEND TO RESPOND TO YOU IN THAT WAY, TO SEEK YOUR SUPPORT, AND TO BE AN ACTIVE PARTNER AS WE TRY TO COME TO GRIPS WITH SEEMINGLY INTRACTABLE PROBLEMS UNDER CONDITIONS OF LIMITED RESOURCES. YOUR EXPERIENCE WITH AND INSIGHT REGARDING THE DEPARTMENT'S PROGRAMS ARE EXTREMELY IMPORTANT TO ME, AND I HOPE TO HEAR FROM YOU OFTEN DURING MY TENURE AS SECRETARY.

IN PREPARING FOR THIS HEARING, I HAVE THOROUGHLY REVIEWED THE DEPARTMENT'S BUDGET. ALTHOUGH, AS YOU KNOW, I DID NOT PARTICIPATE IN ITS DEVELOPMENT, I CAN SEE THAT IT ATTEMPTS TO STRIKE A BALANCE BETWEEN THIS ADMINISTRATION'S COMMITMENT TO RESTRAIN SPENDING WHILE PROVIDING SUPPORT TO THOSE WHO DEPEND ON GOVERNMENT FOR BASIC HUMAN NEEDS.

CONSTRUCTING A SATISFACTORY BUDGET IN THE CURRENT ECONOMIC ENVIRONMENT IS EXTREMELY DIFFICULT. I KNOW THAT YOU WILL BE FACED WITH PRESSING CHOICES AMONG COMPETING DEMANDS AS YOU PROCEED TO CONSIDER THE LABOR/HHS APPROPRIATIONS BILL. I WOULD WELCOME THE OPPORTUNITY TO WORK WITH YOU NOW AND IN THE DAYS AHEAD.

THE BUDGET FOR FISCAL YEAR 1984 AS SUBMITTED IN JANUARY OF THIS YEAR TOTALS $285.2 BILLION IN BUDGET AUTHORITY AND $288.8 BILLION IN OUTLAYS, INCREASES OF $11.7 BILLION AND $13.9 BILLION RESPECTIVELY COMPARED TO FISCAL YEAR 1983.

THE HHS BUDGET CONSISTS OF AUTHORITY TO SPEND INCOME TO THE SOCIAL SECURITY AND MEDICARE TRUST FUNDS, AS WELL AS REGULAR APPROPRIATIONS REQUESTS. FOR THE DEPARTMENT'S PROGRAMS CONSIDERED BY THIS SUBCOMMITTEE, OUR APPROPRIATIONS REQUEST FOR 1984 TOTALS $69.4 BILLION. THIS REQUEST ASSUMES THAT CONGRESS WILL ENACT SEVERAL LEGISLATIVE PROPOSALS, WHICH WILL REDUCE THE COST OF HHS APPROPRIATED ENTITLEMENT PROGRAMS BY $0.7 BILLION.

We are also requesting $7.4 billion as fiscal year 1985 advance appropriations, primarily for the Medicaid and Aid to Families with Dependent Children programs.

The projected increase of $13.9 billion, or 5 percent, in outlays will permit the overall budget to keep pace with inflation. However, it represents a substantial reduction from the growth rate of prior years. The HHS budget grew by over 17 percent from 1980 to 1981, or by $34 billion, in just one year. That one year increase was more than the entire HHS budget including Social Security before 1967.

The major features of this budget are:

Implementation of Social Security Recommendations

The budget reflects the recommendations of the bipartisan National Commission on Social Security Reform. These recommendations ensure the timely payment of benefits, preserve the integrity of the Social Security system, and ensure that funding problems of future years will be fairly and equitably met.

None of these recommendations would reduce an individual's current monthly Social Security benefit check.

I applaud the Congress for moving quickly in recently approving this package virtually intact.

Reforming Incentives in the Health Care Financing System

This year's budget assumes passage of reforms designed to slow the increasing costs of Federally financed health care and to keep high quality care affordable for all Americans. While inflation in the general economy is being curtailed, medical care costs are still increasing at an unacceptably high double-digit rate.

The Administration's 1984 health incentive reform proposals address the underlying causes of excessive medical and, particularly, hospital cost increases (19 percent in 1982) in the current health care financing system. These are: cost-based reimbursement, poorly structured cost-sharing and open-ended tax subsidies for high cost health insurance.

THE MAJOR REFORM PROPOSALS ARE:

- A RESTRUCTURING OF MEDICARE COVERAGE TO PROTECT THE ELDERLY FROM THE CATASTROPHIC COSTS OF UNUSUALLY LONG AND EXPENSIVE ILLNESS BY REMOVING EXISTING LIMITS ON THE NUMBER OF COVERED HOSPITAL DAYS AND REDUCING PATIENT COST-SHARING ON LENGTHY HOSPITAL STAYS.

- MEDICARE COINSURANCE ARRANGEMENTS WOULD BE CHANGED AND NOMINAL COPAYMENTS REQUIRED UNDER MEDICAID IN ORDER TO ENCOURAGE BENEFICIARY COST CONSCIOUSNESS AND PREVENT UNNECESSARY UTILIZATION. ADDITIONALLY, THE PREMIUM UNDER THE MEDICARE PHYSICIAN AND NON-HOSPITAL PROGRAM (PART B) WOULD BE RAISED TO MOVE THE PROGRAM CLOSER TO THE ORIGINALLY INTENDED--EQUAL--BALANCE BETWEEN BENEFICIARY PREMIUM PAYMENTS AND GENERAL REVENUES. FURTHER, THE PART B DEDUCTIBLE WOULD BE INDEXED TO THE MEDICARE ECONOMIC INDEX IN FUTURE YEARS IN ORDER TO PRESERVE ITS ECONOMIC VALUE AS A DETERRENT TO UNNECESSARY UTILIZATION.

- A PROSPECTIVE PAYMENT SYSTEM WHICH WOULD SET HOSPITALS' PAYMENT RATES UNDER MEDICARE IN ADVANCE AND REWARDS HOSPITALS FOR EFFICIENT DELIVERY OF CARE. THE CONGRESS HAS ALREADY APPROVED A VERSION OF THIS SYSTEM.

- A VOLUNTARY VOUCHER SYSTEM TO EXPAND OPPORTUNITIES FOR MEDICARE BENEFICIARIES WHO WISH TO USE THEIR BENEFITS TO ENROLL IN PRIVATE HEALTH PLANS THAT OFFER HEALTH SERVICES EQUAL TO OR BETTER THAN MEDICARE COVERAGE AT A LOWER COST.

- OTHER MEASURES TO SLOW THE RISE IN FEDERAL EXPENDITURES FOR MEDICARE AND MEDICAID, INCLUDING PROVISIONS TO LIMIT REIMBURSEMENTS TO PHYSICIANS AND PROVIDE COST-SAVING INCENTIVES.

- WHILE NOT INCLUDED IN THE HHS BUDGET, ANOTHER COMPONENT OF THE ADMINISTRATION'S HEALTH INCENTIVE REFORMS WOULD INCREASE COST CONSCIOUSNESS BY LIMITING THE AMOUNT OF TAX-FREE HEALTH INSURANCE EMPLOYEES CAN RECEIVE FROM THEIR EMPLOYERS. THIS WOULD AFFECT 30 PERCENT OF THOSE AT PRESENT COVERED BY EMPLOYMENT-SPONSORED HEALTH INSURANCE, AND THESE INDIVIDUALS WOULD TYPICALLY FALL IN THE HIGHER INCOME BRACKETS.

These proposals require all participants in Medicare--beneficiaries, hospitals and practitioners--to make some sacrifices but do not inequitably penalize any of them. The resulting savings, including outlay reductions and revenue increases, are $4.3 billion in 1984.

Changes to Income Maintenance Programs

Several changes in the Aid to Families with Dependent Children (AFDC) program will reduce welfare dependency by strengthening employment incentives. Other changes focus AFDC benefits on those most in need by taking into account applicable household resources. Changes in the Child Support Enforcement program will promote increased collections and more cost-effective administration. These will save $0.7 billion in 1984.

Funding of Discretionary Programs

Several important discretionary health and social services programs that represent national priorities are increased over 1983 funding levels, including research activities of the National Institutes of Health and the Alcohol, Drug Abuse and Mental Health Administration; prevention, health protection and health promotion efforts of the Food and Drug Administration and Centers for Disease Control; and Head Start, which will provide services to an additional 29,100 disadvantaged children in 1984.

The budget also proposes lower funding levels for some programs, reflecting targeting of program resources, improved efficiency and/or increased State, local, and private sector support.

Management Improvements

The budget reflects this Department's continued commitment to improve its stewardship responsibilities and to minimize waste, fraud and abuse of taxpayers' dollars, including the following ongoing activities:

o Procedures for collecting debts owed to the Department have been strengthened. We collected $1.2 billion in FY 1982, and we have a goal of $1.6 billion in FY 1984.

- The paperwork burden that HHS imposes on others will decrease by another 2 million hours in 1983. We expect to achieve additional decreases in FY 1984.

- A five-year plan initiated in 1982 to correct serious deficiencies in the Social Security Administration (SSA) computer systems will proceed on schedule. These improvements are designed to ensure prompt and accurate payment of monthly benefits and to improve service to a growing number of beneficiaries.

- The criminal investigations functions of SSA and the Health Care Financing Administration have been transferred to the Office of the Inspector General. This consolidation will strengthen HHS efforts to combat fraud and abuse.

- We will continue to receive the benefit of reforms put in place in 1982 to speed the approval of new prescription drugs, while maintaining high standards of safety and efficacy.

I will now discuss some of the specifics of the budget for each of the Department's operating divisions.

PUBLIC HEALTH SERVICE

For Public Health Service (PHS) programs within this Subcommittee's jurisdiction, we are requesting appropriations of $6.7 billion for 1984.

The budget reflects this Administration's continuing commitment to health research, disease prevention and health promotion, and to support State provision of health services through block grants, with the overall goal of further improving the health status of the U.S. population.

HEALTH RESOURCES AND SERVICES ADMINISTRATION

A total of $324 million is requested for activities of the Health Resources and Services Administration (HRSA) which are considered by this Subcommittee.

THIS REQUEST FOR HRSA EXCLUDES FUNDS FOR AN EXPANDED PRIMARY CARE BLOCK GRANT AND THE MATERNAL AND CHILD HEALTH BLOCK GRANT WHICH ARE REFLECTED IN THE OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH APPROPRIATIONS REQUEST.

HIGHLIGHTS OF THE 1984 HRSA BUDGET INCLUDE:

o NATIONAL HEALTH SERVICE CORPS (NHSC)
THE $96 MILLION REQUEST FOR THE NHSC WILL PROVIDE FOR A FIELD STRENGTH OF 3,283 PHYSICIANS AND OTHER HEALTH CARE PERSONNEL, INCLUDING 1,989 FEDERAL SALARIED ASSIGNEES. THESE INDIVIDUALS DELIVER HEALTH CARE SERVICES TO THOSE LIVING IN AREAS WITH A SHORTAGE OF HEALTH PROFESSIONALS AND PROVIDE ACCESS TO SERVICES FOR UNDERSERVED POPULATIONS, INCLUDING MIGRANT WORKERS.

o HEALTH PROFESSIONS EDUCATION
THE 1984 REQUEST INCLUDES $116 MILLION TO SUPPORT THE TRAINING OF HEALTH PROFESSIONALS. THESE FUNDS WILL BE TARGETED TO A NUMBER OF IMPORTANT NEEDS, INCLUDING:

-- PREPARING HEALTH PROFESSIONALS TO SERVE AN INCREASINGLY OLDER POPULATION AND TO EMPHASIZE HEALTH PROMOTION AND DISEASE PREVENTION FOR ALL PATIENTS;

-- TRAINING PRIMARY CARE PRACTITIONERS;

-- ENCOURAGING HEALTH PROFESSIONALS TO LOCATE IN REMOTE OR UNDERSERVED AREAS;

-- ENCOURAGING MINORITIES TO CHOOSE CAREERS IN THE HEALTH PROFESSIONS; AND

-- IMPROVING THE UTILIZATION AND DISTRIBUTION OF NURSES.

IN ADDITION TO THE BUDGET AUTHORITY REQUESTED FOR 1984, APPROXIMATELY $62 MILLION WILL BE AVAILABLE FOR STUDENT LOANS FROM THE REVOLVING FUNDS AT 1,645 HEALTH PROFESSION AND NURSING SCHOOLS. THESE REPAID LOAN MONIES, COUPLED WITH OUR EFFORTS TO IMPROVE DEBT COLLECTION EFFORTS, WILL ENABLE SCHOOLS TO CONTINUE TO PROVIDE AN ADEQUATE LEVEL OF ASSISTANCE TO NEEDY STUDENTS.

o Health Planning

No funds are requested for health planning agencies in 1984, consistent with the Administration's policy to eliminate ineffective Federal involvement in such planning.

CENTERS FOR DISEASE CONTROL

As the lead public health agency responsible for disease prevention and health promotion, the Centers for Disease Control (CDC) is principally involved in detecting, controlling, and preventing infectious and chronic diseases, environmental and occupational health conditions, and other newly emerging health problems nationwide. This national focus on disease prevention and health promotion efforts is central to the Administration's health policy because it reduces human suffering, enhances the quality of life, and is cost-effective in the long-term.

The 1984 budget request for CDC is $270 million, an increase of $21 million over 1983. Excluded from this total is $85 million for the Preventive Health Services Block Grant which is budgeted under the Assistant Secretary for Health appropriation.

o Immunization

Through CDC's leadership and provision of financial assistance to States for immunization activities, many childhood diseases have been brought almost entirely under control, with immunization levels reaching new highs of about 95 percent, and cases of measles, rubella, tetanus, polio, and mumps reaching all-time lows. For example, the number of reported cases of measles in all of 1982 dropped to only 1,697 nationwide, a further 44 percent reduction from the previous record low reported in the prior year and an 87 percent reduction from the 13,500 measles cases reported in 1980. We have actually had a measles-free week--a notable first in history--in January 1983. However, as the recent outbreak of measles at the University of Indiana attests, complete eradication of this disease in the United States has not yet occurred.

In 1984, $42 million is requested to maintain these record achievements against vaccine-preventable childhood diseases and to continue the development of the vaccine stockpile begun in 1983.

NATIONAL INSTITUTES OF HEALTH (NIH)

The President's FY 1984 budget released January 31 includes $4.1 billion for NIH, an increase of $73 million above 1983. In 1984, it is the Administration's policy to fund 5,000 new and competing research grants. As a result of recent decisions within the Administration on this budget, we are going to provide funding for 5,000 new and competing grants within the pending request of $4.1 billion. We are now in the process of doing the technical budget work to accomplish this goal and will provide details of this work to the Subcommittee shortly.

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION (ADAMHA)

The 1984 budget includes $421 million for the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), the Nation's primary source of basic biomedical and behavioral research funding for the mental health and substance abuse fields. Excluded from this total is $439 million for the Alcohol, Drug Abuse and Mental Health Block Grant which is included in the appropriation for the Office of the Assistant Secretary for Health.

The 1984 request includes a 15 percent increase in research funding, the strengthening of the ADAMHA intramural research program, and increased prevention activity. A total of 500 new research project grants and 1,000 research trainees will be supported in 1984.

Our request maintains the 1983 operational level of St. Elizabeths Hospital while reflecting the strategy, discussed with the Congress last year, to decrease and subsequently end, over a ten-year period, Federal support for services provided to District of Columbia residents. As part of this strategy, we will be submitting legislation to the Congress to establish a corporation to administer the hospital.

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

The 1984 request is $206 million for the programs in the Office of the Assistant Secretary for Health (OASH) and $1,357 million for Health Block Grants.

o Health Block Grants

The 1984 request of $1,357 million for the health block grants includes $85 million for Preventive Health; $439 million for Alcohol, Drug Abuse and Mental Health; $460 million for Primary Care; and $373 million for Maternal and Child Health.

In 1984, the Department proposes to continue consolidating categorical grants for health through legislation to include three additional programs in the Primary Care Block Grant: Migrant Health Services, Black Lung Clinics and Family Planning.

Consistent with Administration policy to simplify and reduce unnecessary Federal oversight of State and local programs, the budget proposes to consolidate administration of the block grants in OASH.

o Other Highlights of the OASH Request Include:

-- $46 million for the National Center for Health Statistics, an increase of $5 million compared to 1983. This level would maintain the 1983 level of key activities in health data gathering, analysis, and dissemination;

-- $16 million for the Adolescent Family Life program, $3 million above 1983. A total of 96 grants would be supported, 19 more than 1983; and

-- $7 million for Health Promotion and Smoking and Health activities, $3 million above 1983.

HEALTH CARE FINANCING ADMINISTRATION (HCFA)

The 1984 HCFA budget request includes outlays of $80.7 billion from both trust funds and appropriations, an increase of 11.4 percent over the current estimate for 1983. This expected increase is due primarily to the continued inflationary rise in health care costs. Approximately 49 million beneficiaries will be served through the Medicare and Medicaid programs in 1984, an increase of 943,000 people compared to 1983.

As mentioned earlier, the 1984 budget and legislative program includes a comprehensive Health Incentives Reform

PACKAGE TO CONSTRAIN THE EXCESSIVE GROWTH IN HEALTH CARE COSTS BY INTRODUCING INCENTIVES TO ENCOURAGE MORE COST-EFFICIENT PROVISION OF NEEDED SERVICES.

IN TOTAL, OUR BUDGET AND LEGISLATIVE PROPOSALS WILL REDUCE PROJECTED FEDERAL MEDICARE AND MEDICAID OUTLAYS UNDER CURRENT LAW BY $2.1 BILLION IN 1984. HOWEVER, THESE PROGRAMS STILL GROW BY $8.9 BILLION IN THE BUDGET YEAR.

FOR HCFA PROGRAMS WHICH REQUIRE APPROPRIATIONS ACTION, PRIMARILY MEDICAID AND A PORTION OF THE MEDICARE PROGRAM, WE ARE REQUESTING APPROPRIATIONS OF $38.1 BILLION IN 1984.

MEDICAID

THE 1384 APPROPRIATIONS REQUEST FOR THE MEDICAID PROGRAM IS $20.7 BILLION, AN INCREASE OF $1.4 BILLION OVER OUR CURRENT ESTIMATE FOR FY 1983. THIS INCREASE OF ONLY 7.1 PERCENT REFLECTS THE STATES' CONTINUING EFFORTS TO CONTROL RISING PROGRAM COSTS. THE REQUEST IS BASED ON NOVEMBER 1982 COST ESTIMATES OF THE STATES AND INCLUDES THE IMPACT OF PROPOSED LEGISLATIVE SAVINGS OF $0.3 BILLION. THESE LEGISLATIVE PROPOSALS ARE DESIGNED TO PRESERVE QUALITY HEALTH CARE WHILE STIMULATING MORE COST-CONSCIOUS BEHAVIOR, MAINTAIN INCENTIVES TO MODERATE PROGRAM GROWTH AND IMPROVE THE EFFICIENCY OF PROGRAM OPERATIONS.

PAYMENTS TO HEALTH CARE TRUST FUNDS

A TOTAL OF $17.3 BILLION IS REQUESTED FOR THE PAYMENTS TO THE HEALTH CARE TRUST FUNDS APPROPRIATION, AN INCREASE OF $1.9 BILLION ABOVE 1983. THIS ACCOUNT REPRESENTS THE PAYMENT PRINCIPALLY FOR FEDERAL MATCHING OF PREMIUMS FOR INDIVIDUALS ENROLLED IN THE MEDICARE SUPPLEMENTARY MEDICAL INSURANCE (SMI) PROGRAM (MEDICARE PART B).

THE GROWTH IN THE FEDERAL PAYMENT FOR THE PART B PROGRAM IS PRIMARILY A RESULT OF RISING PROGRAM COSTS AND THE NEED TO KEEP THE PROGRAM ACTUARIALLY SOUND. WE HAVE PROPOSED LEGISLATION TO MAINTAIN THE ECONOMIC VALUE OF THE PART B DEDUCTIBLE, AND TO INCREASE THE PREMIUM TO COVER 25 PERCENT OF PROGRAM COSTS IN 1984, GRADUALLY INCREASING TO 35 PERCENT BY 1988. WHEN THE MEDICARE PART B PROGRAM WAS FIRST ESTABLISHED, BENEFICIARY PREMIUMS COVERED 50 PERCENT OF PROGRAM COSTS WITH THE REMAINDER FINANCED FROM GENERAL REVENUES. THIS PROPOSAL TO INCREASE THE

PREMIUM WOULD MOVE THE PROGRAM TOWARD THE ORIGINAL BALANCE BETWEEN BENEFICIARY PREMIUM PAYMENTS AND GENERAL REVENUES.

PROGRAM MANAGEMENT

THE 1984 BUDGET INCLUDES $83 MILLION IN APPROPRIATIONS AND $1,062 MILLION IN TRUST FUND TRANSFER AUTHORITY TO ADMINISTER THE MEDICARE AND MEDICAID PROGRAMS. HIGHLIGHTS OF HCFA PROGRAM MANAGEMENT ACTIVITIES INCLUDE:

o PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS (PSROs) AND PEER REVIEW ORGANIZATIONS (PROs)

NO FUNDS WERE REQUESTED IN THE PRESIDENT'S BUDGET FOR PSRO/PRO ACTIVITY IN 1984. HOWEVER, SINCE THAT TIME, THE CONGRESS, IN APPROVING A PROSPECTIVE PAYMENT SYSTEM FOR MEDICARE, HAS MANDATED FUNDING FOR PRO ACTIVITY IN FY 1984. ACCORDINGLY, WE ARE REASSESSING OUR BUDGET IN THIS AREA, AND WILL ADVISE YOU OF ANY CHANGES WHICH ARE NECESSARY.

o MEDICARE CONTRACTORS

THE 1984 BUDGET REQUEST OF $837 MILLION IS AN INCREASE OF $17 MILLION OVER THE 1983 LEVEL. NINETY PERCENT OF THE BUDGET REQUEST, OR $751 MILLION, IS ALLOCATED TO ESSENTIAL CLAIMS-PROCESSING SERVICES. THE REQUEST ALSO PROVIDES $112 MILLION FOR PAYMENT SAFEGUARD ACTIVITIES (AUDITS AND MEDICAL UTILIZATION REVIEWS) WHICH RESULT IN SAVINGS IN MEDICARE BENEFIT PAYMENTS IN MULTIPLES OF THE ADMINISTRATIVE COSTS EXPENDED. THE TAX EQUITY AND FISCAL RESPONSIBILITY ACT OF 1982 AUTHORIZED $45 MILLION TO BE SPENT IN EACH OF THREE YEARS BEGINNING IN 1983 FOR AUDITING PROVIDER COST REPORTS AND FOR INCREASING MEDICAL UTILIZATION REVIEWS. OUR BUDGET REQUEST REFLECTS THIS AUTHORIZATION. FINALLY, THE BUDGET INCLUDES SAVINGS FROM EFFICIENCY IMPROVEMENTS MADE IN 1983 AND PRIOR YEARS AND REFLECTS COSTS AND SAVINGS FROM SIMILAR IMPROVEMENTS REQUESTED AS PART OF THE 1984 BUDGET. PRODUCTIVITY INVESTMENTS MADE IN 1982-1984 ARE EXPECTED TO SAVE THIS PROGRAM $100 MILLION THROUGH 1988.

o STATE CERTIFICATION

THE 1984 BUDGET REQUEST OF $73 MILLION PROVIDES FOR SEMI-ANNUAL INSPECTIONS OF THE ESTIMATED 35 PERCENT OF HEALTH CARE FACILITIES HAVING SEVERE DEFICIENCIES, WHICH, IF NOT CORRECTED, COULD THREATEN THE HEALTH AND SAFETY OF BENEFICIARIES. THE REQUEST SUPPORTS SURVEYS OF FACILITIES WITH LESS SEVERE

DEFICIENCIES AND INSPECTIONS OF FACILITIES WITH GOOD COMPLIANCE HISTORIES EVERY TWO YEARS. APPROXIMATELY 80 PERCENT OF SKILLED NURSING FACILITIES WOULD BE SURVEYED IN 1984.

SOCIAL SECURITY ADMINISTRATION

THE FISCAL YEAR 1984 BUDGET FOR THE SOCIAL SECURITY ADMINISTRATION'S (SSA) INCOME SECURITY PROGRAMS FOR THE AGED, DISABLED AND POOR TOTALS $194.7 BILLION IN OUTLAYS FINANCED BOTH THROUGH TRUST FUNDS AND GENERAL FUND APPROPRIATIONS. ALMOST 50 MILLION PEOPLE WILL RECEIVE BENEFITS FROM THESE PROGRAMS IN FY 1984.

AS MENTIONED EARLIER, THE BUDGET FOR SOCIAL SECURITY FULLY REFLECTS THE RECOMMENDATIONS OF THE NATIONAL COMMISSION ON SOCIAL SECURITY REFORM.

FOR PROGRAMS SUBJECT TO APPROPRIATIONS, WE ARE REQUESTING $19.0 BILLION, AS FOLLOWS:

SUPPLEMENTAL SECURITY INCOME:

THE FISCAL YEAR 1984 APPROPRIATIONS REQUEST FOR THE SUPPLEMENTAL SECURITY INCOME (SSI) PROGRAM TOTALS $7.9 BILLION. THIS IS A $0.7 BILLION DECREASE FROM FY 1983, RESULTING FROM PAYMENT OF TWO FEWER BENEFIT CHECKS IN FY 1984 THAN IN FY 1983. FY 1984 HAS FEWER CHECKS BECAUSE THE FIRST DAY OF FY 1984 FALLS ON A WEEKEND WHICH MEANS THAT THE FIRST BENEFIT CHECK FOR FY 1984 WILL BE PAID IN FY 1983 AND, THEREFORE, IS FINANCED WITH FY 1983 RESOURCES.

THE SSI REQUEST INCLUDES AN INCREASE OF $341 MILLION IN 1984 WHICH IS THE NET AMOUNT PRINCIPALLY NEEDED TO FUND THE RECOMMENDATION BY THE NATIONAL COMMISSION ON SOCIAL SECURITY REFORM TO DISREGARD AN ADDITIONAL $30 OF SOCIAL SECURITY (OASDI) INCOME EFFECTIVE JULY 1, 1983 AND A PROPOSAL TO POSTPONE THE COST-OF-LIVING ADJUSTMENT BY 6 MONTHS-FROM JULY 1983 TO JANUARY 1984. (SINCE THE PRESIDENT'S BUDGET WAS SUBMITTED, THE CONGRESS, IN ENACTING THE SOCIAL SECURITY REFORM BILL, HAS APPROVED A $20 PER MONTH PAYMENT INCREASE FOR BENEFICIARIES ($30 FOR COUPLES), RATHER THAN THE DISREGARD PROPOSAL.)

ASSISTANCE PAYMENTS:

A TOTAL OF $7.1 BILLION IS REQUESTED IN 1984 FOR THE ASSISTANCE PAYMENTS (AFDC) APPROPRIATION. REFLECTED IN THIS TOTAL IS $722 MILLION IN SAVINGS ASSOCIATED WITH SEVERAL LEGISLATIVE CHANGES PROPOSED IN THE BUDGET.

THESE LEGISLATIVE PROPOSALS BUILD UPON THE REFORMS ENACTED BY THE CONGRESS IN THE OMNIBUS BUDGET RECONCILIATION ACT OF 1981 AND THE TAX EQUITY AND FISCAL RESPONSIBILITY ACT OF 1982, AND ARE DESIGNED TO REDUCE WELFARE DEPENDENCY BY STRENGTHENING EMPLOYMENT INCENTIVES AND TO TARGET ASSISTANCE TO THOSE MOST IN NEED BY ENSURING THAT PAYMENTS BETTER REFLECT TOTAL HOUSEHOLD RESOURCES AND ACTUAL LIVING EXPENSES.

CHILD SUPPORT ENFORCEMENT:

THE 1984 APPROPRIATIONS REQUEST FOR CHILD SUPPORT ENFORCEMENT (CSE) TOTALS $416 MILLION, INCLUDING $10 MILLION IN SAVINGS ASSOCIATED WITH A PROPOSAL TO ENHANCE STATE INCENTIVES FOR INCREASING COLLECTIONS AND FOR OPERATING COST-EFFECTIVE PROGRAMS. AN ADDITIONAL $145 MILLION IN SAVINGS IN MEDICAID AND AFDC IS PROJECTED FROM OTHER PROPOSALS TO STRENGTHEN STATE CHILD SUPPORT ENFORCEMENT PROGRAMS, AND BY REQUIRING STATE AGENCIES TO SEEK MEDICAL SUPPORT FROM ABSENT PARENTS FOR THEIR CHILDREN.

LOW-INCOME HOME ENERGY ASSISTANCE:

THE 1984 BUDGET FOR LOW-INCOME HOME ENERGY ASSISTANCE INCLUDES $1.3 BILLION IN BLOCK GRANTS TO STATES FOR ASSISTANCE TO LOW-INCOME HOUSEHOLDS FOR THEIR HEATING COSTS, WEATHERIZATION, CRISIS ASSISTANCE AND SOME COOLING COSTS.

LEGISLATION WILL BE PROPOSED FOR THIS PROGRAM TO MORE PRECISELY DIRECT FUNDS TO STATES WHICH HAVE THE MOST SEVERE HOME ENERGY NEEDS AND THE GREATEST CONCENTRATION OF LOW-INCOME FAMILIES. THIS LEGISLATION WILL ALSO GIVE STATES ADDED FLEXIBILITY IN DETERMINING INCOME ELIGIBILITY REQUIREMENTS AND PAYMENT LEVELS, AND WILL REDUCE FEDERAL REPORTING REQUIREMENTS.

Refugee and Entrant Assistance:

In 1984, the budget includes $485 million for refugee and entrant assistance programs, a decrease of $93 million compared to 1983. This reduction reflects:

- o A decline in refugee eligibility for cash and medical assistance and social services due to exhaustion of time-limited eligibility. It is estimated that approximately 410,000 refugees will be eligible for assistance in 1984, a reduction of 22 percent compared to 1983;
- o An estimated ten percent reduction in refugee admissions; and
- o A parallel reduction in the need for social services and other assistance as the eligible refugee population declines.

In 1984, the Department proposes to consolidate funds now earmarked for social services, targeted assistance, educational assistance, and cash and medical assistance to noncategorically eligible refugees into a grant to States to be awarded on a per-capita basis. This consolidated grant would give States the flexibility to allot funds among these program areas as needed. No budget reduction is associated with this consolidated grant.

Limitation on Administrative Expenses:

The Limitation on Administrative Expenses appropriation provides resources for SSA to administer the Old Age, Survivors and Disability Insurance programs, the Supplemental Security Income program, and certain health insurance functions.

For 1984, we are requesting authority to spend $3.7 billion, a net increase of $0.2 billion over 1983. This increase is principally due to higher costs for salaries, State agency disability workloads, and data processing.

OFFICE OF HUMAN DEVELOPMENT SERVICES AND OFFICE OF COMMUNITY SERVICES

We are requesting $5.3 billion in appropriations for programs to be administered by these offices in 1984.

THE BUDGET FOR THESE PROGRAMS REFLECTS:

- o TARGETING FEDERAL SUPPORT ON THE MOST IMPORTANT DIRECT SERVICE ACTIVITIES, AND
- o ENCOURAGING INCREASED STATE, LOCAL AND PRIVATE SECTOR SUPPORT OF PROGRAMS.

SOCIAL SERVICES BLOCK GRANT:

THE 1984 BUDGET REQUEST FOR THE SOCIAL SERVICES BLOCK GRANT IS AT THE AUTHORIZATION LEVEL OF $2.5 BILLION. NO FUNDS ARE REQUESTED FOR THE COMMUNITY SERVICES BLOCK GRANT WHICH SERVES SIMILAR PURPOSES. A HIGHER PRIORITY IS PLACED ON THE SOCIAL SERVICES BLOCK GRANT, WHICH PROVIDES STATES WITH GREATER FLEXIBILITY BECAUSE IT CONTAINS FEW RESTRICTIONS AND EARMARKS. THIS FLEXIBILITY ALLOWS STATES TO TAILOR SERVICES AND ACTIVITIES MOST APPROPRIATE TO THE UNIQUE SOCIAL AND ECONOMIC NEEDS OF THEIR RESIDENTS.

HEAD START:

THE 1984 BUDGET INCLUDES $1,051 MILLION FOR THE HEAD START PROGRAM, AN INCREASE OF $62 MILLION OVER 1983. THIS LEVEL WILL SUPPORT SERVICES TO 424,900 CHILDREN, 29,100 MORE THAN IN 1983. OF THESE, AT LEAST 10 PERCENT, OR MORE THAN 42,000, WILL BE HANDICAPPED.

IN PREVIOUS YEARS, HEAD START PROJECTS HAVE RECEIVED REIMBURSEMENTS FROM THE DEPARTMENT OF AGRICULTURE'S (USDA) CHILD CARE FEEDING PROGRAM TO HELP PROVIDE NUTRITIOUS MEALS TO CHILDREN. IN 1984, $76 MILLION FOR NUTRITION IS BEING REQUESTED DIRECTLY IN THE HEAD START PROGRAM, APPROXIMATELY THE SAME LEVEL AS ESTIMATED FUNDING IN FY 1983.

AGING PROGRAMS:

A TOTAL OF $998 MILLION IS REQUESTED FOR AGING SOCIAL SERVICES AND NUTRITION PROGRAMS.

INCLUDED IN THIS AMOUNT IS FUNDING FOR TWO PROGRAMS WHICH ARE PROPOSED FOR TRANSFER TO HHS FROM OTHER DEPARTMENTS: COMMUNITY SERVICE EMPLOYMENT FOR OLDER AMERICANS FROM THE DEPARTMENT OF LABOR, AND THE ELDERLY FEEDING PROGRAM FROM THE

DEPARTMENT OF AGRICULTURE. LOCATING ALL OF THESE PROGRAMS IN A SINGLE FEDERAL AGENCY AND PROVIDING THE FUNDS THROUGH STATE AGING AGENCIES WILL SIMPLIFY PROGRAM ADMINISTRATION AT FEDERAL, STATE AND LOCAL LEVELS.

THE BUDGET REQUEST WILL PROVIDE SUPPORT FOR:

- o AN ESTIMATED 9 MILLION PARTICIPANTS IN AGING PROGRAMS. THESE INDIVIDUALS WILL HAVE ACCESS TO A FULL RANGE OF COMMUNITY SERVICES, INCLUDING INFORMATION AND REFERRAL, TRANSPORTATION AND COUNSELING. OF THESE, AN ESTIMATED 4.7 MILLION WILL BE LOW INCOME PARTICIPANTS;

- o 670 AREA AGENCIES ON AGING AND 57 STATE AGENCIES;

- o AN ESTIMATED 191 MILLION MEALS IN BOTH CONGREGATE SITES AND THROUGH HOME DELIVERY, THE SAME LEVEL AS IN 1983; AND

- o INDIAN TRIBES AT A LEVEL OF $5.7 MILLION, THE SAME AS IN 1983.

FAMILY SOCIAL SERVICES:

THE 1984 BUDGET INCLUDES $601 MILLION FOR PROGRAMS TO KEEP FAMILIES TOGETHER, SUPPORT CHILDREN WHO CANNOT CONTINUE TO LIVE WITH THEIR FAMILIES, ENCOURAGE PERMANENT PLACEMENT OF FOSTER CHILDREN, AND PROVIDE ADOPTIVE HOMES WHEN REUNIFICATION OF CHILDREN AND FAMILIES IS NOT POSSIBLE.

THE BUDGET INCLUDES $156 MILLION FOR CHILD WELFARE SERVICES AND TRAINING; $440 MILLION, THE ESTIMATED ENTITLEMENT LEVEL, FOR FOSTER CARE; AND $5 MILLION FOR ADOPTION ASSISTANCE.

WORK INCENTIVES (WIN):

THE 1984 BUDGET DOES NOT INCLUDE FUNDS FOR THE WORK INCENTIVE (WIN) PROGRAM BECAUSE IT HAS NOT PROVEN TO BE COST-EFFECTIVE. IN ITS PLACE AN ALTERNATIVE WORK PROGRAM IS BEING PROPOSED FOR AFDC RECIPIENTS.

UNDER THIS PROPOSAL, EMPLOYABLE AFDC APPLICANTS AND RECIPIENTS WILL BE REQUIRED TO PARTICIPATE IN JOB SEARCH AND OTHER EMPLOYMENT-RELATED ACTIVITIES AS A CONDITION OF AFDC ELIGIBILITY. THE DEPARTMENT WILL PROVIDE FUNDING TO STATES FOR

THE ADMINISTRATIVE COSTS OF THESE ACTIVITIES UNDER THE AFDC PROGRAM'S REGULAR 50 PERCENT MATCHING RATE. AT THE SAME TIME, OTHER PROGRAMS, SUCH AS THE SOCIAL SERVICES BLOCK GRANT, WILL ALSO ALLOW STATES TO PROVIDE ADDITIONAL SOCIAL AND EMPLOYMENT SERVICES TO AFDC RECIPIENTS WHO ARE UNABLE TO PURSUE EMPLOYMENT OPPORTUNITIES THROUGH REGULAR STATE EMPLOYMENT SERVICES.

FURTHER JUSTIFICATION FOR NOT FUNDING THE WIN PROGRAM IS CONTAINED IN A JUNE 1982 REPORT OF THE GENERAL ACCOUNTING OFFICE (GAO). THIS REPORT INDICATES THAT, WHILE WIN MAY MARGINALLY INCREASE THE INCOMES OF SOME PARTICIPANTS, IT DOES NOT HELP MOST WIN REGISTRANTS ATTAIN ECONOMIC INDEPENDENCE, AND THAT THE PERCENT OF WIN PARTICIPANTS WHO LEAVE WELFARE IS PROBABLY NO HIGHER THAN WOULD BE EXPECTED WITHOUT THE PROGRAM. GAO ALSO IDENTIFIED SEVERAL DEFICIENCIES IN THE MEASURES USED TO EVALUATE WIN'S EFFECTIVENESS, INCLUDING THE DOUBLE-COUNTING OF PARTICIPANTS WHO ENTERED MORE THAN ONE JOB IN A GIVEN YEAR, AND USING JOB RETENTION PERIODS OF LESS THAN 6 MONTHS TO DEFINE THE NUMBER OF WIN PARTICIPANTS WHO WERE SUCCESSFUL IN MAINTAINING EMPLOYMENT.

DEPARTMENTAL MANAGEMENT

THE 1984 BUDGET REQUEST FOR THOSE ACTIVITIES CONDUCTED UNDER THE DEPARTMENTAL MANAGEMENT HEADING TOTALS $289 MILLION. WITHIN THIS TOTAL, THE GENERAL DEPARTMENTAL MANAGEMENT APPROPRIATION SUPPORTS THE EXECUTIVE LEADERSHIP OF HHS, AND SPECIALIZED OPERATIONAL SERVICES WHICH ARE PERFORMED CENTRALLY FOR ALL OF THE DEPARTMENT'S OPERATING DIVISIONS. ALSO INCLUDED IN THIS CATEGORY ARE APPROPRIATIONS FOR THE INSPECTOR GENERAL, THE OFFICE FOR CIVIL RIGHTS, AND POLICY RESEARCH. AT THIS LEVEL, DEPARTMENTAL MANAGEMENT COSTS REPRESENT ONE-TENTH OF ONE PERCENT OF THE TOTAL HHS BUDGET.

THAT CONCLUDES MY STATEMENT. I WILL NOW BE HAPPY TO ANSWER YOUR QUESTIONS.

BIOGRAPHY OF MARGARET M. HECKLER

Margaret M. Heckler was sworn in as secretary of health and human services March 9, 1983, by Supreme Court Justice Sandra Day O'Connor. She was nominated by President Reagan Jan. 12, 1983, and confirmed by the Senate March 3, 1983.

As head of the Department of Health and Human Services, Mrs. Heckler oversees the federal agency most concerned with the health, welfare, food and drug safety, medical research and income security programs serving the American people.

Mrs. Heckler had served 16 years in the U.S. House of Representatives from Massachusetts' 10th Congressional District after being elected in 1966 to the first of her eight terms. She was the senior ranking woman in Congress.

In the House, Mrs. Heckler served on the Joint Economic Committee, Science and Technology Committee, Veterans' Affairs Committee and the Select Committee on Aging. She held key positions on various subcommittees as vice chair of Agriculture and Trade, ranking Republican on Education, Training and Employment, and second ranking GOP member on Hospitals and Health Care. On these committees, Mrs. Heckler was heavily involved in legislation on health care, child care, nutrition and geriatrics. She authored Title III of Public Law 96-330, Geriatrics, Research and Health Care, which established geriatric centers within the Veterans Administration. As a member of the Banking Committee she authored the Equal Credit Opportunity Act which ensured women equal access to credit. In 1976, as one of 11 women in Congress she was the co-founder of the Congressional Caucus for Women's Issues which she co-chaired through 1982.

Mrs. Heckler began her political career as the first woman elected to the Commonwealth of Massachusetts' Governor's Council on which she served two terms before her election to Congress.

She was born Margaret Mary O'Shaughnessy in Flushing, N.Y., June 21, 1931. She attended Albertus Magnus College from which she received her Bachelor of Arts in 1953. She was selected as U.S. student representative to the University of Leyden, Holland. She attended Boston College Law School, was an editor of the Law Review there and was the only woman in the graduating class of 1956.

After college, Mrs. Heckler practiced as a trial attorney. She is a member of bar associations of many states, and has been admitted to practice before the U.S. Supreme Court.

Her affiliations have included: member, National Commission on the Observance of International Women's Year; past president, Catholic Women's College Alumnae Association; and member of the American Bar Association's Committee on Banking and Business dealing with Food, Drug and Cosmetic Laws.

Among Mrs. Heckler's honorary degrees are those from: Northeastern University, Stonehill College, Emmanuel College, Regis College, St. Bonaventure University, Boston College, Wheaton College and Assumption College.

She has been married for 30 years to John M. Heckler and they have three children: Belinda, Alison and John.

Questions Submitted by the Subcommittee

LEGISLATIVE SAVINGS

Question: Madame Secretary, your Department's budget seems to be filled with proposals to save money through new legislation which you expect this Committee to approve. For example, your budget asks us to --

-- Eliminate the Health Planning program,

-- Cap the health professions guaranteed loan program below the authorized level,

-- Put a limit on National Health Service Corps loans,

-- Authorize the Secretary of HHS to use her discretion to determine the allocation formula to be used under the Low Income Energy Assistance Program,

-- Authorize mandatory co-payments by Medicaid beneficiaries in place of the optional co-payments authorized just last year; and

-- Reduce AFDC benefits by $722 million through a series of proposed changes to the Social Security Act.

I'm sure we could go on and on with other examples.

Have you submitted these and other legislative proposals to the Senate Labor and Human Resources and Finance Committees which are the proper places for them to go?

Answer: First of all, our proposals to eliminate or reduce funding for discretionary programs -- such as health planning, health professions, and low income energy -- do not require legislation. There is no requirement to fund discretionary programs and funding levels for these programs are set annually by the Congress at any level (below the authorized level) the Congress determines.

On the other hand, funding levels for entitlement programs are set in the authorizing legislation, and new legislation is needed to change these levels.

With respect to our legislative proposals, much of our legislative proposals have been sent to the Congress and some have already been enacted. Social Security reform was passed by the Congress last month, including provisions affecting the Supplemental Security Income program. Our Medicaid and Medicare proposals were sent to the Congress in February and a prospective payment system under Medicare has already passed.

Other major proposals which are before the Congress include: the Public Health Service amendments that reauthorize program appropriation authorities and improve program administration, including the proposal to add 3 programs to the Primary Care Block Grant; the Maternal and Child Health Block Grant Amendments; Health Loan Default Amendments; and Child Abuse and Adoption Opportunities.

Most of the remaining legislative proposals will be sent to Congress during April.

Question: What reaction have you gotten?

Answer: As you know, the Congress acted very quickly in approving the Social Security Amendments of 1983, including a Medicare prospective payment system. Several of our other proposals are now under active consideration by the Congress.

With respect to the balance of our proposals, Congress has not yet initiated work.

Question: If Congress doesn't go along with your so-called legislative savings, what next? How much more money would be required to appropriate?

Answer: As I mentioned earlier, the legislative proposals affecting the discretionary programs would have no effect on the amount of our appropriations request.

The FY 1984 appropriations request for the entitlement programs includes a total of $0.7 billion in savings associated with our legislative proposals, as follows:

	(Dollars in millions)
Medicaid	-$300
Supplemental Security Income	+341
Aid to Families with Dependent Children	-722
Child Support Enforcement	-10
Total	-$691

Excluding the impact of the Supplemental Security Income proposals which have already been acted on in the context of the Social Security Amendments, an additional $1.0 billion would be needed if the remaining entitlement proposals are not enacted.

STAFF REDUCTIONS ASSOCIATED WITH HEALTH BLOCK GRANTS

Question: Isn't the proposed shift just an excuse to fire a lot of the expert staff that we need to run these very sensitive programs? What else could we possibly deduce when we see that you plan to abolish some 435 positions related to the Primary Care and Maternal and Child Health Block Grants in addition to proposing some highly controversial changes in the blocks?

Answer: As we have proposed to complete the conversion of these programs to block grants, we have also proposed commensurate reductions in the staff associated with the current management of these categorical project grants. We estimate that only 20 positions will be needed to oversee each of the block grants and supply the necessary level of financial and administrative services. The block grants require far fewer staff because Federal planning and grant-making responsibilities are virtually eliminated and for a good reason; States are far fewer equipped to do the

job. The only Federal responsibility which should be maintained is a general fiduciary one. We have already completed a similar process of phasing out staff providing detailed, direct Federal management of categorical programs for those programs now consolidated into the Alcohol, Drug Abuse and Mental Health block, the Preventive Health block, and for all the programs, except the national research and demonstration activities, consolidated into the Maternal and Child Health block.

BLOCK GRANT ENFORCEMENT

Question: It has been about a year and a half since passage of legislation authorizing the establishment of block grants. Congress clearly reaffirmed the national policy objective of ensuring nondiscrimination in Federal assistance programs by inclucing specific civil rights language in most block grant titles of the Reconciliation Act.

It is my understanding that your preliminary draft of implementing rules fails to include prohibitions of discrimination. In addition, it appears that you have instructed your program offices to use existing data, and they have been directed that "under no circumstances were they to contact the States for any data."

If the Department does not plan to contact the States to obtain data, how will it obtain data which is adequate?

Answer: As you know, all Federal funds -- including the block grants -- are subject to the non-discrimination provisions of the basic civil rights laws. This is true whether the block grant statutes cite these laws or not. No new rules are necessary to implement the fundamental civil rights statutes, i.e., Title VI of the Civil Rights Act of 1969 (prohibits discrimination on the basis of race, color, or national origin); Title IX of the Education Amendments of 1972 prohibits discrimination on the basis of sex in education programs; section 504 of the Rehabilitation Act of 1973 prohibits discrimination on the basis of handicap); and the Age Discrimination Act of 1975 (prohibits discrimination on the basis of age).

The block grant statutes repeat the prohibitions against discrimination cited in these statutes, and the health block grants also contain prohibitions of discrimination based on religion. Discrimination on the basis of sex is specifically prohibited in each of the block grants except the Social Services Block Grant.

The preamble to the Department's final regulations for the HHS block grants issued on July 6, 1982, made it clear that existing civil rights regulations apply to all the block grants, including the Social Services block. They also stated that regulations implementing novel provisions of the block statutes--i.e., non discrimination based on sex or religion--were being developed. The Department's regulation implementing these provisions was approved by Secretary Schweiker and are now being reviewed by the Equal Employment Opportunity Commission and the Department of Justice, as required. They will be published as

soon as we have their concurrence. I wish to add that the Department will be submitting proposed legislation to make the statutory language of the block grants more uniform in relation to non-discrimination, for example, by establishing prohibitions against discrimination based on sex and religion in the Social Services Block grant and Low Income Home Energy Assistance program.

Answer: As I mentioned, the final regulations implementing the block grants make it clear that existing non-discrimination regulations apply to all the blocks, but that new regulations will be developed for the novel aspects of the blocks, principally, the prohibitions against discrimination on the basis of sex and religion. As these prohibitions are new HHS jurisdictions, regulations to deal with these complex issues had to be developed. Former Secretary Schweiker approved a draft notice of proposed rulemaking for these prohibitions which was sent to the Equal Employment Opportunity Commission (EEOC) and the Department of Justice in February for comments and approval. EEOC has reviewed the document and suggested a few changes which will be incorporated. The Department of Justice's comments are expected momentarily. The Department will then send the NPRM to the Office of Management and Budget for their review. Once that is completed the NPRM will be issued and will allow for a 60-day public comment period after the publication date in the Federal Register. Subsequent to that a final rule will be prepared and published.

As regards your concern that the Department will not have sufficient data for civil rights enforcement, let me assure you that we will have such information. First, there has been no change in civil rights enforcement procedures for the blocks, except that once a violation has been found. States have 60 days to consider it before we take action directly. As I mentioned, the existing civil rights regulations remain in effect. The Department's civil rights staff has and will continue to investigate alleged civil rights violations. All recipients of Federal funds are required to respond to the Secretary if information or reports showing the extent to which members of the affected groups receive services under HHS programs, are deemed, by the Secretary, to be necessary to show compliance. Where complaints indicate that there are potential problems, I will not hesitate in requiring this information.

Second, information on State compliance procedures with civil rights provisions will be collected during our annual compliance reviews in selected States, as required under statutes for several of the blocks.

Finally, concerning data collection on the block grants generally, we will continue to collect the necessary data to address congressional and HHS need for information on State operation of the blocks. We have not prohibited our agencies from contacting the States for data. We have made it clear, however, that we will only gather data that meets a legitimate Federal need for information. The block grant statutes limit the Federal role in data collection and we are restricting our activities to those which are necessary to Federal purposes.

Question: What mechanism is now in place by which you evaluate services under the block grants, particularly with respect to discrimination in the use of funds?

Answer: As you know the primary responsibility for evaluating the block grants rests with the State and its citizenry. Congress included several provisions in the block grants aimed at ensuring that the citizens of the State had sufficient information to assess the appropriateness and adequacy of the services provided with block grant funds. Congress provided for a very limited Federal role in assessing State operation of the blocks; one that is directed to ensuring State compliance with statutory provisions. Through the annual compliance reviews required in five of the block grants, through our review of State pre- and post-expenditure reports, through our review of State audits and through our investigation of complaints, we will ensure State compliance with the block grant statutes, as well as the civil rights statutes.

Question: When do you plan to have regulations on this matter firmed up and will they contain adequate safeguards against discrimination?

BIOMEDICAL RESEARCH

Question: One of the most important enterprises under your jurisdiction is the National Institutes of Health. The NIH is the most significant institution of its kind in the world and represents all of our hopes for conquering cancer, heart disease, and other afflictions that bring pain, misery and death to so many people each year.

We now know from your statement that the Administration has decided to support 5,000 new and competing research grants in fiscal 1984 rather than the 3,676 shown in your budget, but you propose to do so without increasing the overall dollar level of the budget. How much will this approach cost other important NIH initiatives such as continuation grants, clinical trials, training, research centers, etc.?

Answer: The decision to fund 5,000 new and competing research project grants within the same dollar level required a hard look at NIH funding mechanisms. The revised estimates focus resources on the core functions and responsibilities of NIH, the most important of which is the generation of new biomedical knowledge through investigator-initiated research project grants. This redirection of resources required reductions totalling $140.9 million in other mechanisms as well as increasing the downward negotiations in the direct costs of new and competing grants from 6 percent in the January estimates to 10 percent.

The following mechanisms were affected by the decision to fund 5,000 grants:

- Specialized/comprehensive research centers provide the necessary environment for studying specific investigative and clinical problems and for translating the leads generated by basic research into application. The

current plan eliminates 53 renewal centers from the draft budget and provides for further downward negotiations in the noncompeting centers, for a total reduction of $49.3 million.

- The BRS program awards funds to research institutions based on their level of PHS research grant support. These funds complement project grants by providing for pilot projects, support of new investigators, and shared instrumentation. This program is reduced by $24.2 million from the January estimate, but the shared instrumentation part of the program will not be decreased.

- The current plan calls for eliminating the 5 percent stipend increase that was contained in the January estimate for research training awards. This reduction amounts to about $4.6 million.

- Noncompeting research project grants have been reduced by $17 million from the January estimate. The resulting average cost represents a 6 percent downward negotiation from full commitment levels, compared to 5 percent negotiations in the January estimate.

- Research and development contracts are reduced by $20.2 million from the January estimates.

Other changes from the January estimates include the elimination of support for the Gorgas Memorial Institute ($1.9 million), and reductions of $2.0 million in General Clinical Research Centers, $2.1 million in research career programs, $2 million in the NCI clinical education program, $1.8 million in cooperative clinical research, $7.8 million in administrative supplements to research project grants, $3.4 million in intramural research, $0.6 million in direct operations, and $2.9 million in Buildings and Facilities projects.

Question: The President's budget was sent to the Hill on January 31 -- and you are proposing this new budget some two months later. What took you so long?

Answer: As was indicated in former Secretary Schweiker's letter which accompanied the draft January budget, the Administration was committed to the support of 5,000 competing research project grants. The issue which needed to be resolved was how best to accomplish this within the many competing demands for the Federal dollar. Numerous discussions were held between the Department and the OMB before final resolution. Because of the complexity of the issue, a considerable length of time was required to achieve the final decision.

Question: How do you view your stewardship of the NIH -- and what do you think the government's role in biomedical research should be?

Answer: Since becoming Secretary, DHHS, I have been working diligently to chart the course for continued progress in the health of this Nation. As I view it, NIH and its programs represent a

major part of a nationwide collaborative research network created chiefly through a multibillion dollar public investment. The Federal investment supports an estimated 90 percent of all basic biomedical research in this country and has contributed greatly to what is termed "biological revolution" in the health sciences. Today's knowledge and technology are enabling us to pursue greater fundamental knowledge and methods to prevent and treat our major maladies.

As Secretary, my goal is to ensure that the opportunity for significant health benefits will continue to flow from this research enterprise. It will remain a significant and essential element during my Administration.

Question: Your fiscal 1984 NIH budget proposes less than a 2 percent increase over fiscal 1983 at a time when we understand that costs of conducting biomedical research will be going up by 5.3 percent to 5.5 percent. How do you justify such a small increase?

Answer: Given the growing budget deficit, it is imperative to constrain the growth in Federal spending and to look for ways to achieve economies even in our highest priority programs.

The fact that only a 1.8 percent increase is provided for NIH will mean belt-tightening. It will mean that priority decisions will be sharper, that difficult trade-offs will have to be made, and that funds will be concentrated on the most important activities.

The FY 1984 budget affords highest priority to research project grants, the recognized medium of breakthrough for many fundamental discoveries. Through a process of fine-tuning, NIH has reevaluated resource allocations among its funding mechanisms and yet maintained the priority placed on the generation of new biomedical knowledge within the funding constraints. A slightly larger share of the total NIH budget will be devoted to these grants than in FY 1983 (52.5 percent vs. 51.3 percent). Within the overall 1.8 percent increase, the aggregate average cost of new and competing grants will increase by approximately 2.8 percent and the average cost of continuations will increase by 3.6 percent. I believe these increases will ensure that the Nation's capacity for biomedical research is not compromised.

COMBINING SOCIAL AND COMMUNITY SERVICES BLOCK GRANTS

Your budget proposes abolishing the Community Services Block Grant, which is currently funded at $373 million for fiscal year 1983, based on the premise that this program duplicates the Social Services Block Grant.

Question: In the light of the fact that the budget request is $548 million below existing appropriations for these two programs, what evidence is there that services to impoverished individuals currently provided by the Community Services Block Grant will not be adversely affected by consolidation with the Social Services Block Grant?

Answer: States are currently targeting most of their Social Services Block Grant funds to low income populations. To assure that this focus continues, the Social Services Block Grant legislation will be amended to add a sixth goal that focuses on alleviating poverty. It is likely that States will continue to target funds to support services to impoverished individuals.

Question: Wouldn't this proposed cutback put the States in the position of having to curtail existing social services activities — such as child care and elderly nutrition, in order to maintain anti-poverty projects of Community Action Agencies?

Answer: States will continue to have the flexibility in choosing to provide services to meet various priorities. High priority is given to services categorized as life-sustaining such as protective services, in-home services, and other services designed to prevent institutionalization.

Question: If you want to eliminate the Community Services Block Grant, why don't you propose repeal of the authorizing legislation?

Answer: Legislation will be proposed to repeal the Community Services Block Grant.

WORKFARE

Question: A number of States have voluntarily set up "workfare" demonstration programs, which the Administration now proposes to require for welfare recipients in all States. Yet, a January 1983 GAO report indicates that information is not yet available on how "workfare" demonstration projects are working. If this is the case, isn't it premature to propose making the program mandatory?

Answer: Although the amount of information obtained from our demonstration projects has been limited, we have received sufficient information from States operating our workfare programs (Community Work Experience Programs--CWEP's) to confirm our belief in their value. This information, which is discussed in more detail below, has shown that a CWEP helps improve employability of AFDC recipients and reduce welfare dependency. Also, the initial CWEP results have been consistent with those achieved by earlier work experience programs; for example, in Utah's Work Experience and Training program, 35 percent of the participants had their welfare cases closed or grants reduced as the result of obtaining employment.

Also, information provided by the States indicates that costs of operating these programs are manageable. Several States are reporting costs ranging from $20 to $40 per participant per month.

Question: What information do you have that indicates how successful the workfare demonstration programs have been in moving people into unsubsidized jobs and reducing welfare costs?

Four States (Oklahoma, New York, North Carolina, and West Virginia) have reported that 20-30 percent of their CWEP participants are entering employment.

In these States where the State welfare agency has implemented strong, comprehensive work programs, placements in regular employment are running substantially above the levels achieved by WIN. For example, Oklahoma is reporting placements about 200 percent above the level previously reported under WIN. New York State reported that the "entered employment" rate for CWEP participants was running about 60 percent above the rate for WIN registrants and that program savings exceed costs by about 2 to 7.

We believe that making welfare recipients more employable will be a major factor in the lowering of welfare costs. Other factors include deterrence of individuals who have come to view welfare as an alternative to work and sanctions of individuals who refuse to cooperate. Although deterrence is very difficult to measure, New York estimated that its CWEP requirements were deterring about 9 percent of the potential participants. New York and North Carolina reported sanction rates in the range of 10 to 15 percent, but sanction rates seem to vary considerably from State to State.

Question: If your proposed "workfare" legislation is enacted, how many more welfare recipients will be placed in permanent jobs, over and above the number that would otherwise find jobs?

We cannot estimate the number of recipients who would be placed into jobs because the available data do not distinguish between cases diverted because of job placements and those diverted for other reasons. Our estimate is of the total effect of the work requirements.

Question: How does your estimate compare to placements under the Work Incentive program that is being eliminated?

As stated previously, we did not separately estimate the number of recipients who would be placed into jobs; our estimate was based on the total effect of the program in reducing welfare dependency. We believe the proposed program will be more effective in promoting this overall goal than the Work Incentive Program (WIN) has been. However, available evidence from States with workfare demonstrations indicate that movement of people into unsubsidized jobs will be a major component of this overall success. Data from those States (cited previously) indicate that job placement rates in the programs are substantially greater than had been achieved in WIN programs.

ACQUIRED IMMUNE DEFICIENCY SYNDROME

The nation has become aware of the increasing number of persons afflicted with Acquired Immune Deficiency Syndrome, AIDS, which carries a very high mortality rate. We understand that as of March of this year there are 1,112 victims and 418 deaths throughout the country.

Question: We know that Departmental agencies are playing key roles in the attack on AIDS, but what assurances can you give us that HHS is making an all-out effort?

Answer: The AIDS investigation continues to receive very high priority at the Centers for Disease Control, the National Institutes of Health, and the Food and Drug Administration. The concerted efforts of these Public Health Service agencies are focused on identifying the causal agent, determining high risk factors, conducting epidemiologic and laboratory investigations, and developing preliminary control strategies.

Current efforts to combat AIDS include:

- o CDC: Disease surveillance, epidemiologic studies to determine high risk factors, and laboratory investigations to detect the cause of AIDS, and interim prevention recommendations. CDC is also reviewing the efficacy of potential screening tests.

- o NIH: Intramural research including clinical studies on treatment modes and investigations on the immunology profiles of healthy homosexuals and hemophiliacs. Extramural research efforts focus on investigating possible causal agents, sequelae of AIDS, the national history of the syndrome, the possible relationship between AIDS and hepatitis. Efforts are directed also to cellular immunology and the regulation of the immune system.

- o FDA: Reviewing blood product processing techniques for ways to eliminate risks of infection, especially for hemophiliacs.

Although the cause of AIDS remains unknown, PHS has issued recommended interim steps to reduce the risk of exposure. These steps are directed at educating groups at increased risk of harboring AIDS to the potential danger to others, and at restricting the use of plasma from risk groups in the manufacture of certain plasma derivatives. These steps are appropriate until satisfactory procedures are developed to identify the individuals whose blood may be at risk, thereby protecting not only the quality of blood but preventing any harmful disruption of the supply to the much larger public needing transfusions. More definite scientific information is required before stronger control and regulatory steps are indicated.

Question: How well coordinated are your efforts? Do you have an intra-HHS working group and do you participate in any government-wide efforts?

Answer: There is regular interagency communication through the AIDS working groups of the Centers for Disease Control (CDC), the National Institutes of Health (NIH), and the Food and Drug Administration (FDA). These PHS agencies have shared information about the AIDS problem and progress on investigations on an ongoing basis, and have participated in collaborative meetings held in October 1981, March 1982, July 1982, and January 1983. The Assistant Secretary for Health has provided leadership as chairman

of these meetings. Several other smaller conferences have been held involving selected officials of the CDC, NIH, and FDA to discuss AIDS investigations.

Question: We have seen a March 22 letter from Dr. Wyngaarden, head of the National Institutes of Health, indicating he expected that total Public Health Service expenditures on AIDS in fiscal year 1983 will be $10.1 million and $9.3 million in fiscal year 1984. That doesn't seem like much, but perhaps you have another view on it. Do you?

Answer: You may be certain that the Public Health Service is vigorously pursuing all avenues of approach to this problem. Since the March 22, letter a revised assessment has been made of the funds being expended for AIDS. Total PHS expenditures for AIDS now are expected to be $14.1 million in 1983 and $17.1 million in 1984.

Question: Is the outbreak of AIDS comparable in seriousness to Legionnaires' Disease -- or is it worse?

Answer: The total estimated number of legionnaire's cases and deaths annually exceeds the number of AIDS cases and deaths. However, the AIDS outbreak is felt to be very serious because the number of cases continues to increase. The current mortality rate for all AIDS cases is 38 percent but the mortality rate exceeds 80 percent in cases diagnosed over two years ago.

Question: Where are we on controlling Legionnaires' Disease?

Answer: Case-control studies of sporadic legionellosis are in progress. Current field studies includes investigations into the modes of transmission of legionellosis and the evaluation of control measures relating to potable water; industrial aerosols; and aerosols from whirlpools, respiratory therapy equipment, and cooling towers. Methods for identification of Legionella agents are undergoing constant improvement and resulting technologies are being transferred to commercial reagent manufacturers and to clinical laboratories. Molecular biology technologies are being utilized to produce both new materials for research and new materials for use in rapid and specific diagnosis. The Second International Meeting on Legionellosis, June 19-23, Atlanta, Georgia will provide a forum to discuss the newest findings, evaluate progress in control and prevention, and plan future control efforts.

HEALTH PROFESSIONS TRAINING

Madame Secretary, one of the important activities under your jurisdiction is the health professions training program. The program is designed to assure the nation an adequate supply of health professionals as well as to bring their services to medically underserved areas.

Question: How do you view your and the Department's roles in the health professions field -- to continue to develop an assured supply of trained individuals, or to cut and finally get rid of the program?

Answer: This Administration, as early as February 1981, has taken a position of continued Federal involvement in health professions training. During the past, the Department's role in health professions education has been characterized by increasing the aggregate output of health professionals. That role is no longer necessary since aggregate supply is no longer a problem. The challenge for the future is to anticipate and address the more complex problems of assuring that the proper types of health professional personnel are distributed and utilized in the most appropriate way and that these personnel are educationally prepared to provide quality services to a changing population.

Question: Your fiscal 1984 budget proposes to reduce funding for health professions training by almost $60 million. This looks like about a 32 percent cutback. Isn't that a pretty good signpost for the direction you're taking?

Answer: Although there is a substantial reduction of the Health Professions Training programs in the FY 1984 budget, the Department will continue anticipating future needs in health professions training, utilization and practice addressing the areas just mentioned. Targeted Federal technical or financial assistance will be provided in those fields where it is most needed and where other resources are not available.

ADOLESCENT FAMILY LIFE

At the end of fiscal year 1982, the Adolescent Family Life Program received a $10.3 million supplemental appropriation and, with those funds, awarded 50 demonstration grants and 12 research grants.

Question: By what method do you ensure that grantees will not violate the ban of mentioning abortion to teenagers seeking assistance? Where would a teenager seeking information with respect to abortion be referred?

Answer: The Adolescent Family Life legislation specifically prohibits abortion and abortion counseling or referral, except when an adolescent, and her parents or guardians, request referral for abortion counseling. In this instance, the project refers the adolescent and her family to an agency in the community that includes abortion counseling within its range of services. The program carefully monitors grantees to assure that Federal funds are being used to provide needed services and not for activities prohibited by the statute.

Question: How do you respond to charges that some of the awards to religious groups "Promote Religion With Federal Funds"?

Answer: The Adolescent Family Life legislation authorizes the funding of projects to help pregnant teenagers, their children and families and to reach teenagers before they become sexually active. All of the applicants funded sought funds for these purposes only. In the monitoring of the projects, program staff ensure that Title XX funds are used only for the purposes authorized by the law.

Question: While in comparison to other programs, funds requested for this activity are small, I would still like to know why this merits a 21.7% increase over FY 1983? (from $13.4 - $16.3 million)

Answer: The Administration is concerned about the significant rise in adolescent premarital sexual activity and conception during the past decade. The level of premarital pregnancy among teenagers doubled between 1971 and 1976 and increased another one-fourth by 1979. The Adolescent Family Life program with its research and model demonstration approach is a critical element in our efforts to address these problems.

The $13.4 million appropriated in FY 1983 enabled the program to establish model programs around the country and fund research projects. These care and prevention projects explore family centered approaches to the problems surrounding adolescent premarital sexual activity and pregnancy. Research projects help us to understand the causes of adolescent pregnancy and contribute immediately to the design of better services.

The $2.9 million increase will be used to enhance the program in several ways. First, funds will be used to develop new demonstrations for areas of the country that still need local care and prevention models. Second, funds will be used to establish programs of national significance illustrating the family centered orientation of the Adolescent Family Life Program. Third, evaluations will be done on all nationwide as well as on individual projects to ensure that funds are effectively used. Fourth, funds will support new research in areas we need to understand better, such as the effect of popular culture on adolescent sexual activity and the decline in adoption.

Question: How do you respond to charges that "the awards went to only one minority applicant and by-passed many inner-city areas where the problem of unwed mothers is particularly acute"?

Answer: The Adolescent Family Life program was enacted by Congress to provide models for communities around the country to demonstrate effective care services for pregnant adolescents and adolescent parents and prevention services to reach young people before they become sexually active. The program realizes that different approaches work for different communities so that models are designed to address the various needs of urban or rural communites, adolescents of all ages and diverse populations groups.

Specifically regarding the concern of minority applicant awards, the program is funding a variety of demonstration projects under the sponsorship of minority organizations that are designed for the needs of minorities within the populations served. Examples of such projects are: Norfolk State University (Norfolk, Virginia), a traditionally Black institution that is providing family day care, parenting classes, and educational health and social services for pregnant adolescents and adolescent parents; Hill Health Corporation (New Haven, Connecticut), a community-controlled health center with a comprehensive adolescent clinic and a Family Togetherness

Program; Economic Opportunity Family Health Center (Miami, Florida), an ambulatory health care center providing both prevention and care services to people residing in multi-family low income housing projects; and, Providence Ambulatory Health Care Foundation, Inc. (Providence, Rhode Island), a network of six ambulatory health care facilities providing services to the inner-city, low income, ethnic community of Providence.

"Baby Doe"

Question: Certainly one of your constituencies are infants born with severe handicaps that they may have to carry around the rest of their lives. Our attention is drawn to the case of an infant who was born in Bloomington, Indiana, apparently with Down's Syndrome and other medical complications. Following a favorable court ruling, food was withheld from the infant and it finally died. As a result, your Department issued the very controversial "Baby Doe" rule requiring hospitals to provide adequate nutrition and medical care in such cases or face possible loss of Federal funds. You've also directed that anyone with knowledge of alleged violations call in the information on a telephone hotline number.

You stepped into a very delicate area. Who did HHS consult in the medical, legal or even religious fields before issuing a no-exceptions rule that could have such profound implications?

Answer: First, it should be understood that the March 7, 1983 interim final rule merely established a requirement that recipient hospitals post a notice advising the public that Section 504 of the Rehabilitation Act of 1973 prohibits discrimination on the basis of handicap and the means established to report suspected violations. The rule does not change the substantive obligations of recipients of Federal financial assistance to refrain from discrimination. That obligation already exists under the statute and the HHS regulations issued pursuant to Section 504. On May 18, 1982, the Department reminded recipients that under Section 504, it is unlawful to withhold nutritional subtenance and life-sustaining medical treatment on the basis of handicap, unless such treatment is medically contraindicated.

With respect to consultations with other people, HHS had the benefit of medical advice from the Surgeon General and legal advice from the Department of Justice. In addition, the interim final rule provided for a 60-day public comment period.

Question: To what extent should decisions to save, or not save, a gravely ill infant's life be left up to the attending physician and the parents — or do you believe that the Department of HHS should be the final arbiter no matter what the circumstances of the case?

Answer: Most patient care decisions for infants and children are made by the parents and physician, without governmental involvement. The government only gets involved when necessary to carry out

a statutory obligation. With respect to HHS, involvement is based on implementation of Section 504 to assure that medically indicated treatment is not withheld solely on the basis of handicap. State child protective services agencies may become involved to carry out their statutory duties of preventing neglect of children.

Question: Your action, of course, implies that you have more than just momentary concern for the lives of the infant involved. What plans do you have for seeing to it that such infants--most of them incapable of ever helping themselves--will receive appropriate care for the rest of their lives?

Answer: The responsiblity for caring for these infants rests not just with the government, but with all components of society. As is the case with any other handicapped person, there is a wide range of resources available to care for handicapped infants throughout their lives. These resources are available not only in the Federal government, but in State and local governments and in the many private-sector service agencies and foundations which serve the needs of the handicapped. It should also be pointed out that it is incorrect to assume that handicapped persons will always be "incapable of ever helping themselves."

At the Federal level, we are strengthening programs which help provide care and rehabilitation for the disabled. For example, in programs for the developmentally disabled we are shifting funds from non-direct service activities, such as State Grant administration and planning, to direct service activities such as Special Projects and University Affiliated Facilities. In the block grants, our proposals would allow States to more effectively target aid to mothers at risk and to families in need. Similarly, we are proposing changes in Medicaid which will make that program more efficient and effective and better ensure that the medically needy will be able to count on help when it is most needed.

I also believe that as this issue attains wider recognition in our society, we can expect a better understanding of the difficulties faced by parents of these children and the children themselves. This in turn can lead to greater community support and involvement in the lives of its citizens who are less fortunate. Through the cooperative efforts of government, private service organizations and society in general, I believe the life-long needs of such persons will be met.

Finally, while it is true that some handicapped persons do require varying degrees of life-long care or services, there are many others who suceed in caring for themselves as productive rather than dependent members of society.

Question: How will this be reflected in your budget?

Answer: The FY 1984 budget reflects our concerns by preserving support for those activities that are most often turned to by the disabled.

Perhaps more than any single budget change, I believe that the substantial decrease in the rate of inflation in an enormous help in ensuring appropriate care for "Baby Doe" cases. As a result of the President's budget and economic policies, this Administration

has started to bring inflation under control. This means that every dollar today has considerably more purchasing power than it did only two years ago. Helping tame inflation, especially in the health care area, together with our FY 1984 budget changes and the cooperative efforts of State and local governments and private agencies and foundations, is the best way to ensure that handicapped infants will receive appropriate care for the rest of their lives.

Question: Your new rule requires that medical and nutritional actions be taken by the hospitals involved to maintain the lives of infants with severe birth defects. Dr. Koop, the Surgeon General, calls this "Protecting the Act of Living." You probably realize that using the most modern medical technology in such cases will be very expensive. Who will pay for all of this, or do you just wash your hands of the whole matter of cost?

Answer: It is not correct to assume that all cases involving possible violations of Section 504 involved medical treatment using very expensive, ultramodern technology. For example, in the Bloomington, Indiana case the treatment required was a relatively simple and almost always a successful operation to require a detached esophagus, an operation that certainly would have been performed had the infant not had Down's syndrome. The relationship between the need for medical care and the cost of that care should be no different for infants than for older children or adults.

As Dr. Koop and I have stressed, our purpose in these matters is indeed not to prolong the process of dying, but to protect the act of living. If a child is born with a treatable, correctible medical condition, it stands to reason that medically indicated treatment should be rendered. We say simply that because such a child may also have Down's Syndrome or some other handicap, it is unlawful to deny medical treatement just because of the handicap.

Some infants, unfortunately, are born with defects for which medical science has no answer. These regrettable exceptions are not the focus of our concern with respect to the applicability of Section 504.

NEW ROLES

Question: Madame Secretary, after a distinguished career as a Member of Congress, you are embarking on a new role as Secretary of Health and Human Services.

Tell us how you see your role as Head of HHS.

Answer: It is clear that I have a varied role as Secretary:

- o I am chief executive officer of the Department, responsible for setting policy and seeing that it is carried out on a day-to-day basis.

- o I am an agent of the President in terms of carrying out Administration policy; likewise I am an agent of the Congress in carrying out the laws which affect our Department, and I have a responsibility for following Congressional intent in the passage of those laws; this responsibility extends to being an effective and efficient manager of resources, trying to minimize fraud and abuse.

- o I have a responsibility to bring to the attention of the President and his immediate advisors what I believe to be significant needs of our program beneficiaries (or potential beneficiaries) that are not being addressed; other needs caused by public health or other emergencies which might affect part or all of the general population; or changes which I believe will allow programs to be carried out more efficiently or effectively; I also have the responsibility to make sure that the President understands the consequences to our beneficiary and other programs of proposed decisions.

- o I have the responsibility for ensuring a maximum cross-fertilization of ideas and program proposals across the Department's Operating Divisions. None of the Department's programs operates without affecting other parts of the Department. For example, changes in the AFDC program almost always affect Medicaid; research into kidney disease by NIH ultimately will affect payments under Medicare for End-Stage Renal Disease. There are literally hundreds of cross-program effects such as these which must be intelligently addressed every day.

- o I believe that I have a role to introduce new ideas to the Department and to promote new ways of addressing existing problems.

- o Finally, I have a responsibility to reach out to the Department's program beneficiaries and the private sector to understand how the money we spend turns into results; to understand the real world problems of beneficiaries; and to strengthen efforts to better address our problems by enlisting the support of the private sector where it is appropriate and beneficial.

Question: What constituencies do you think you represent when you go before OMB and when you meet with the President? Or do you see your role only as representing the government to those who are dependent on HHS programs?

Answer: I believe that I represent the beneficiaries, and potential beneficiaries, of our programs, especially those who depend on us for their means of income and medical support. I also represent the Department's various program directors who provide their best professional advice to me on policies we should follow. In some cases, I also represent State and local government officials who carry out many of our grant programs, and whose advice is invaluable in administration of our legal mandates.

As you know, I also have a Congressional constituency. From my experience in the Legislative Branch and my daily contacts with members of Congress, I am able to bring that point of view to the councils of the Executive Office of the President.

Question: To what extent do you think compassion has a price that must be paid -- or do you believe it's possible to be compassionate without putting more money on the table?

Answer: Both statements are true. It's very accurate to say that the Department's total budget of nearly $289 billion represents a commitment on the part of the taxpayers of this country which, by any measure, is a significant reflection of compassion.

These resources provide for many significant benefits including:

- o Social Security payments to retired workers and/or their survivors;
- o Payments to those who were in the work force but have become disabled;
- o Payments to the aged, blind, and disabled who have no other means of support;
- o Income for single family parents and their children without other means of support;
- o Medical care for the aged and many of the poor;
- o Energy assistance for low income persons;
- o Cash, medical, and other assistance for refugees;
- o Nutrition and other services for the aged;
- o Social services for large groups of our citizens;
- o Payments to disabled coal miners with "black lung" disease;
- o Pre-school education experience for more than 400,000 children through the Head Start program;
- o Health care for mostly low income people through community health centers and maternal and child health facilities;
- o Health care to American Indians and Alaska natives;
- o Mental health, alcohol abuse, and drug abuse services through the ADAMH block grant;
- o Food, drug and medical device regulation;
- o A level of medical and other biomedical research unequalled elsewhere in the world;
- o Expertise in combatting health and environmental emergencies that threaten our citizens.

So, our commitment is significant and represents a notable level of compassion.

Of course, it is possible to do more. And doing more could be said to represent a higher level of compassion. Social Security payments could be increased, Medicaid eligibility could be expanded, provision of health services and health research could be expanded, etc.

The question is whether we can afford to do more; whether the taxpayers are willing to pay more; whether increased expenditures would be counter-productive in rekindling inflation, which has decreased dramatically to the credit of this Administration. This decrease in inflation represents a significant dividend to the beneficiaries of our programs. Given the level of the Federal deficit, current and prospective, it is clearly necessary to restrain the budget, including that of this Department.

IMPACT OF SOCIAL SECURITY LEGISLATION

Question: Congress has now passed Social Security legislation which differs from your budget proposals in such areas as Supplemental Security Income, Medicare, and payments to trust funds.

How soon will you submit budget amendments and detailed justification material reflecting changes mandated by the new Social Security law?

Answer: As you know, the Social Security Amendments of 1983 were just passed by the Congress on March 24. We are in the process of analyzing all the implications of the provisions in this new bill. Once this detailed review is completed, budget amendments will be submitted if necessary.

Question: Can you briefly summarize how the new Social Security legislation alters your budget request?

Answer: There are several provisions of the new law which affect the appropriations which come before this Subcommittee. The major provisions include:

- o Military Service Credits: Section 151 authorizes a payment to the trust funds for all past noncontributory military service credits, and appropriates an unspecified amount which is to be estimated by HHS.

  Under this provision, a lump sum transfer would be made from the General Fund to the Old Age and Survivors Insurance (OASI), Disability Insurance (DI) and Hospital Insurance (HI) Trust Funds within 30 days of enactment.

  We estimate these amounts to be $19.1 billion for the OASDI Trust Funds and $3.5 billion for the HI Trust Fund in FY 1983.

  There would be a partially offsetting decrease affecting our pending FY 1984 appropriations request in FY 1984 of -$420 million in the Payments to the Social Security Trust Funds account. A similar decrease for Payments to the Health Care Trust Funds would occur amounting to -$140 million.

  The bill also authorizes future appropriations for military service credits after 1983 as well as any necessary adjustments to the initial lump sum payment.

- Unnegotiated Checks: Section 152 authorizes a payment in an amount to be determined jointly by HHS and Treasury to restore to the Trust Funds with interest all previously issued checks which have remained uncashed for six months.

  A lump sum transfer is to be made to the OASI and DI Trust Funds as soon as possible after enactment, but has to be authorized first in an Appropriations Act. The estimated effect on the payments to the Social Security Trust Funds appropriation request is +$1.3 billion, and the intent is to provide these resources in FY 1983. Annual appropriation authorizations for payments covering uncashed checks in the future are also included.

- Increase of SSI Benefit Standard and Delay of COLA: Section 401 increases the SSI benefit standard by $20 for individuals and $30 for couples effective July 1, 1983. Section 111 postpones until January the COLA which normally occurs in July.

  The net cost of these provisions is estimated to be $142 million in FY 1983 and $675 million in 1984. The budget request, which was based on the National Commission's proposal for a $30 increase in the OASDI disregard as well as the COLA delay, included a cost of only $385 million in 1984.

- SSI Alert: Section 405 requires notification by July 1, 1984 of all potentially eligible, elderly Title II beneficiaries of the availability of the Supplemental Security Income program. The cost of this provision is not reflected in the budget request and is estimated to be about $10 million in 1984.

- SSI Eligibility of Temporary Residents of Shelters for the Homeless: Section 403 permits payments to previously ineligible individuals who reside in public emergency shelters for the homeless less than 3 months in a 12-month period. The cost of this provision is not reflected in the budget request and is estimated to be approximately $6 million in 1984.

- Delay in Medicare Part B Premium Increase: Section 606 delays the scheduled increase in the Part B premium from July 1, 1983, to January 1984.

  In order to replace lost premium income due to the delay, the general revenue payment to the Part B Trust Fund in 1984 needs to be increased by $519 million.

  This provision, coupled with the reduction in funding for military service credits mentioned earlier, results in a net increase in our pending appropriations request for the Payments to the Health Care Trust Funds account of $379 million:

Lost Premium Income.....	+$519 million
Military Service Credit.....	-$140 million
Net.....	+$379 million

- o Peer Review Organization (PRO): Section 602(f) provides that hospitals must contract with a PRO by October 1, 1984 in order to receive Medicare reimbursement. The amount expended on review costs must be no less than the 1982 level adjusted for inflation. Funds to support this program would be directly transferred from the Medicare trust funds. No funds were requested in the President's budget for this purpose.

- o Administrative Costs: Implementation of the 1983 amendments may also require additional resources for the Social Security Administration Limitation on Administrative Expenses account and the Program Management appropriation of the Health Care Financing Administration. Since this issue is still under review within the Department, no specific assessment of administrative requirements is available at this time.

Question: Do you favor establishment of the Social Security Administration (SSA) as an independent agency?

Answer: No, as a preliminary judgment, I do not favor the creation of an independent agency at this time.

SSA programs, including those funded by direct appropriations -- AFDC, Supplementary Security Income, Low Income Energy Assistance, etc. -- interrelate to a large extent with other HHS programs such as Medicare, Medicaid, and Social Services programs.

In addition, an independent agency for Social Security would be administratively more expensive while its existence would have no appreciable effect on the status of the trust funds and aspects of the program which rightfully are addressed as public policy matters in this country.

As you know, the Social Security Amendments require that a panel of experts, to be appointed by the House Committee on Ways and Means and the Senate Committee on Finance, conduct a study to analyze implementation issues relating to the establishment of an independent agency. This study is due to Congress by April 1, 1984.

I would defer final judgment on this issue until after I have reviewed this report.

MEDICARE CHANGES

Question: Congress has agreed to sweeping changes in Medicare reimbursement. We will move in a series of stages from a cost-based system to Prospective Reimbursement which is based on the Diagnosis of a patient's illness. How rapidly will the Administration move to put this new system into effect -- and what first-year cost savings do you anticipate, if any?

Answer: In the authorizing legislation Congress provided a timetable for implementing the new system. Transition efforts have already begun. Effective October 1, 1983, we will phase in hospitals by their respective cost reporting periods. In regard to program savings, the legislation mandates that the new prospective

payment system be budget neutral; that is, it will achieve the savings already budgeted from the Section 223 total cost limits and rate of increase limits put in place by Section 101 of P.L. 97-248. Those savings total $1.4 billion in FY 1984.

Question: There has been some apprehension expressed that hospitals may seek to increase their reimbursement under the new system by increasing admissions and readmissions and upgrading diagnoses to more expensive categories. What steps, including utilization review, will you take to protect the new system from such possible abuses which could increase Medicare costs?

Answer: Our Admission Pattern Monitoring (APM) plan will identify increases in admissions based upon Medicare billing data, and the medical review agent will determine if the increase is inappropriate. When the medical review agent detects a problem, remedial action will be taken. Actions taken will range from educational efforts to monetary penalties and sanctions for more egregious offenses. HCFA also plans for medical review agents to perform DRG Validations. On-site review of the medical records will be performed to ascertain that the diagnosis used to arrive at the DRG is confirmed by the medical records. Reimbursement amounts will be revised if errors are found. If a pattern is detected, there will be intensified review of certain DRGs, cases of certain physicians, or all cases from a particular provider. Repeat admissions, which result from premature provider-instigated discharges, will be handled also by the quality review system.

Question: It appears that the new Medicare legislation thwarts your efforts to kill PROs. Now, hospitals receiving payments under prospective reimbursement will be required to contract with PROs to review diagnostic information supplied by such hospitals. Are you ready now to give life to the new PROs?

Answer: We intend to implement the law. The new prospective payment legislation effectively requires that the PROs be implemented no later than October 1, 1984. TEFRA, as modified by the Continuing Resolution for FY 1983, requires us to continue to support effective and efficient PSROs until such time as the PRO program is implemented. Once we have completed an assessment of our financial needs for assuring an orderly transition to the PRO program, we will be pleased to provide this information to you.

OFFICE FOR CIVIL RIGHTS POSITION REDUCTION

Question: It is my understanding that in spite of the fact that the Office for Civil Rights anticipates an increase in the number of new complaints which will be filed during the next fiscal year, OCR plans a staff reduction of 15 positions which, your justification explains, "reflects the general policy of the Administration to economize and to limit Federal employment."

What factors entered into the determination that 15 fewer positions would be required?

Answer: The Office for Civil Rights (OCR) will continue to allocate the same number of positions to complaint investigations in fiscal year 1984 as was allocated to this area in fiscal year 1983. The loss of positions will be absorbed in the legal services and

support areas and will not reduce the agency's core compliance activities. The need for legal services and other support has diminished due to OCR's increased emphasis on voluntary compliance and outreach.

Question: As you well know, Congress was sold the idea of shifting to block grants on grounds that any program cuts would be offset by reductions in costs of administering the blocks. An overhead savings of more than 20 percent was used as the bait. Recently, GAO completed a study of five pre-Reagan block grants that shows that the costs of running three of the five were within the range of the costs of administering categorical programs.

To what extent was the idea of overhead savings under the Reagan blocks oversold -- and where did the Administation come up with the savings figure of more than 20%?

Answer: The Administration's block grant proposals were predicated on a number of benefits, including but not limited to savings in overall administrative costs. The primary benefit was, of course, to allow the citizens of the State and not the Federal government, determine what services to provide and how best to provide them. Administrative savings are, however, an important benefit and we are confident that significant savings have been realized to this point and more will be forthcoming as States take greater advantage of the opportunity to change administrative structures built up in response to prior Federal requirements.

The September 1982 GAO study of the pre-1981 block grants is in many respects not relevant to the blocks enacted by the Omnibus Budget Reconcilliation Act of 1981. The GAO study points out that the pre-1981 blocks "bore only a slight resemblance to their predecessors." In contrast, the new blocks consolidated programs covering activities which the States were already administering.

Furthermore, the GAO study concluded that since the new blocks have fewer Federal requirements than the earlier blocks "reductions in Federal requirements may result in economies not seen previously."

The estimate of 20 percent on overhead was made by some members of the National Governors Association when asked how much the States could save by administering block grants in lieu of categorical programs. It is important to note, however, that these comments were made in reference to administering block grants less restrictive than those finally passed by Congress in the Omnibus Budget Reconcilliation Act of 1981.

While it is too early to judge the extent of administrative savings due to increased flexibility and reduced reporting requirements, the pending GAO evaluation of block grants, as well as other Federal and non-Federal studies, will help us determine the magnitude of these savings.

SECRETARY'S DRIVER

Question: A recent General Accounting report showed that the chauffeur for the Office of the Secretary was paid $35,000 during 1981.

How many chauffeurs are utilized by the Department?

Answer: The Department does not employ any chauffeurs. The individual GAO noted in its report was reassigned in July, 1982, from the Immediate Office of the Secretary to the Office of the Secretary, Transportation Section, where he became one of ten motor vehicle operators constituting the Motor Pool.

The assignment of that driver to the Motor Pool produced several positive results: (1) it reduced overtime and night differential pay; (2) by staggering shifts, more than one driver would be available to drive the Secretary; and (3) drivers could be used for other assignments when not required for the Secretary.

Question: What are their annual salaries?

Answer: During calendar year 1983, four motor vehicle operators shared driving assignments for the Secretary. The estimated costs of labor directly attributable to driving the Secretary during this period was $29,380, including overtime.

Question: Who is authorized to use this chauffeur service?

Answer: As I mentioned earlier, the Department does not employ a chauffeur. The Secretary is the only official in the Department who is authorized portal to portal service from the drivers in the Motor Pool.

"BABY DOE"

Question: The Subcommittee is concerned as to whether your "Baby Doe" regulation could ever lead to a situation where a doctor in a delivery room will have to make a choice between meeting your requirement and saving the life of a gravely ill mother.

We can conceive of a small hospital in a rural area with a limited staff that is on notice from HHS. There could well be other possibilities. Which one would you advise the hospital to save: the infant or the mother?

Answer: It is difficult to understand the basis of this concern. The conduct which section 504 prohibits is discrimination on the on the basis of handicap. The rule of law is that medical treatment decisions should be based on medical factors and necessary, not on the basis of prejudices against handicapped persons.

Question: The President's Commission for the Study of Ethical Problems in Medicine in it's recent report seemed to disagree with the parents and doctor in the Bloomington case, but did say that the HHS rule was "likely to be ineffective and to lead to excessively detailed regulations that would involve government reimbursement officials in bedside decision making." Doesn't that suggest that for an Administration that wants to do away with government regulation and government interference in private decision making, you're marching off in the wrong direction?

Answer: This Administration is committed to reducing unnecessary government burden on the public, but not at the expense of violating

basic rights of handicapped infants. To agree that discrimination against the handicapped should not occur and to enforce the law that prohibits such discrimination,I believe, is marching in the right direction. Furthermore, the applicable law in this case was adopted in 1973 and has been in force for 10 years. Our policy merely makes more explicit what Congress intended when it passed that law.

Question: In an editorial of March 21, the Wall St. Journal said: "It would be a shame if (the Department's) intervention proved more harmful than beneficial to human life." I think the editorial was trying to tell us that there are an awful lot of questions to be answered before anyone agrees that the Department's rule is the last word on the subject. What's your comment on this--and what are you doing to make certain that your course of action is the right one?

Answer: We hope the new regulation is not the last word on the subject, and that it will stimulate increased attention by the medical community, State and local governments and concerned citizens on this problem. In addition, in connection with the public comment period provided with the interim final rule, HHS welcomes all suggestions for possible improvements to the rule.

ELDERLY EMPLOYMENT PROGRAM

Question: Your budget includes $277 million to replace the Labor Department's older worker program, which is currently funded at $319 million. Why are you asking the Appropriations Committee to abolish the existing Labor Department program, and give you funding for a replacement program, when you haven't yet submitted legislation detailing the proposal you have in mind?

Answer: We expect to submit in the near future a legislative proposal to the Congress which will describe in detail the expanded employment and economic development program for older workers that we have in mind. We wanted to make sure that our proposals for this program were reflected in our budget proposal as well.

Question: If your proposal were enacted, can you assure us that none of the elderly persons currently enrolled in the Labor Department programs would be laid off?

Answer: We share your concern about currently enrolled older persons, and our legislative proposal is being drafted to ensure to the greatest extent possible that these individuals are kept on the rolls. We are planning a transition period from the current funding distribution to one more equitable across the states, and one of the main purposes of the transition would be to address this concern.

Question: Would national contracts with such groups as the Farmer's Union and Retired Teachers Association organizations that currently administer the bulk of the Labor Department program, be terminated under your proposal?

Answer: Yes, we will be proposing that the administration of the program shift from the current contractor arrangement to

the State and area agency on aging network. However, each area agency on aging could, if it so elected, enter into arrangements with any of the current national contractors to carry out activities within its planning and service area. Each area agency on aging is presently required under Title III to develop within its planning and service area a comprehensive and coordinated system of supportive and nutrition services for older persons. The proposal to place employment and economic development activities under the jurisdiction of each area agency will broaden the capacity of each area agency to carry out its statutory mandate to develop a comprehensive and coordinated system of services for older persons which is: designed at the community level; based on local determination of needs; and developed with the involvement of older persons through the area agency advisory council.

TRANSFER OF INDIAN PROGRAMS

Question: What are your plans for the Administration for Native Americans (ANA) now that Congress has mandated that its activities continue to be operated through your Department?

Answer: The Administration for Native Americans will continue through the remainder of fiscal year 1983, to administer social and economic development projects to Federally-recognized tribes and non-federally recognized groups who have been successful in the ANA competitive grant review process. In fiscal year 1984, the Department will propose the transfer of the administration of grants to Federally-recognized tribes through the Bureau of Indian Affairs (BIA). The Administration for Native Americans will administer the planned phase-out non-federally recognized grantees, including urban Indians, rural off-reservation Indians without federal recognition and Native Hawaiian groups over the next three years. Budget requests for these groups will be reduced by one third in fiscal year 1984 and another third in fiscal year 1985 and will be zero in 1986.

Question: Why are you proposing to phase-out support for "non-federally recognized Native Americans" even though the authorizing legislation clearly mandated services to this population?

Answer: The Native American Programs Act of 1974, P.L. 93-644, as amended, authorizes rather than mandates that non-federally recognized groups are eligible to be considered for ANA financial assistance grant awards. The proposed phase-out for ANA non-federally recognized grantees includes urban Indians, rural off-reservation Indians without federal recognition and Native Hawaiian groups. Current ANA funded projects to non-federally recognized groups are expected to accomplish results that are lasting and do not require ongoing Federal support. An additional consideration is that communities served through these projects fall within the jurisdiction of State and local governments. These groups will be eligible to be considered under the reduced levels in fiscal year 1984, and 1985, and are also eligible to be served through block grants and categorical programs to states, and discretionary programs to state or local governements.

"CONGRESSIONAL RELATIONS/RUBLIC AFFAIRS RESOURCES"

Question: Please identify the organizational element with primary responsibility to the Secretary for the preparation of the budget and for its presentation to the Congress. What resources are requested in fiscal year 1984 for this purpose?

Answer: The Office of the Deputy Assistant Secretary for Budget under the direction of the Assistant Secretary for Management and Budget has primary responsibility to the Secretary for the preparation and presentation of the HHS budget to Congress. The FY 1984 budget request for the Office of Budget is $2,402,000 and 56 positions.

Question: How many staff years do you have in the Office of the Assistant Secretary for Legislation devoted to working with the Appropriations Committees? How much is requested in fiscal year 1984 for this purpose?

Answer: The Department's staff with primary responsibility for working with the Appropriations Committees are located in the Office of Budget, within the Office of the Assistant Secretary for Management and Budget. In addition, to ensure consistency among the Department's extensive legislative contacts with all elements of the Congress, the Office of the Assistant Secretary for Legislation (ASL) has liaison responsibilities with all committees, including Appropriations in both the House and Senate. Approximately one staff year in ASL is programmed for these appropriations responsibilities.

Question: How many staff years do you have in each of your agencies and bureaus (including the Social Security Administration and the Institutes of NIH) who have responsibility for working with the Appropriations Committees? Identify the amount requested for each.

Answer: The Department's agencies and bureaus are not assigned responsibilities for working directly with the Appropriations Committees. In the course of budget presentation and justification, and consideration by the Appropriations Committees of the budget, a large number of program and budget staff from the agencies and bureaus spend time in participating in this process.

Question: Provide the same information with respect to staff years for public information and public affairs responsibilities for each agency and bureau.

Answer: There are no public information or public affairs staff in the Department which have responsibilities for working with the Appropriations Committees.

DEBT COLLECTION

Question: Madame Secretary, can you tell us how much delinquent debt is owed the Department of Health and Human Services, how much of that debt the Department collected last year and what your debt collection targets are for the current fiscal year as well as fiscal year 1984?

Answer: At the beginning of fiscal year 1982, the Department's delinquent debt was $1,059 million. During the fiscal year, we reduced that debt through collections by $205 million and through write-offs by $27 million to a balance of $827 million as of September 30, 1982. During the first quarter of fiscal year 1983, this delinquent debt was further reduced by $128 million (including $14 million in write-offs) to $699 million.

The Department's overall debt collection goal, including delinquent and non-delinquent debt, is $1.4 billion in the current fiscal year and $1.6 billion in fiscal year 1984 excluding any write-offs that may be necessary. Actual collection of debt in FY 1982 totaled $1.2 billion.

Question: Is the Department using collection agencies to collect delinquent debt? If so, how much is the Department spending on this activity currently and how much do you plan to spend next year?

Answer: The Department is currently piloting the use of a commercial collection agency to collect debt owed the Public Health Service (PHS) after in-house due diligence efforts are unsuccessful. Approximately $4 million in overdue debt owed the Health Education Assistance Program, the National Health Service Corps, and the Physician's Shortage Area Scholarship program are being collected under this pilot contract. Compensation to the contractor, paid directly by PHS, is 9.45 percent of the dollar amount actually collected by the contractor during the 24 months under the contract. Through March 1983, PHS had received collections of $90 thousand and had paid the contractor a fee of 8.5 thousand. Later in this fiscal year, PHS plans to contract for additional services to collect overdue debt in these same programs at a fee to be negotiated.

Question: Does the Department routinely charge interest on delinquent debt?

Answer: The Department is charging interest on all debt not repaid within 30 days after notice that the debt is due, except overdue debt owed the Social Security Administration. Most of the debt on which interest is being charged is the result of audit findings, or debt owed the Public Health Service under its Health Professions and Nursing Student Assistance programs.

Question: Does the Department currently notify credit bureaus of the fact that a debtor is delinquent?

Answer: Currently the Department is not notifying credit bureaus of the fact that a debtor is delinquent. However, procedures are being developed to notify credit bureaus of delinquent debtors under those programs having such authority under the Debt Collection Act of 1982.

Question: Section five of Public Law 97-365 allows you to collect debts due the government by Departmental employees through a salary offset mechanism. Are you currently using this authority?

Answer: We are currently collecting salary overpayments, overdue travel related debt, child support, and alimony indebtedness

(upon receipt of court orders) through salary offset. Procedures are being developed to collect all debts due the government by Departmental employees through a salary offset mechanism.

Question: How many HHS employees are currently being assessed for delinquent debt?

Answer: We are currently assessing 1,377 HHS employees for salary overpayments, 14 HHS employees for travel related delinquent debt, and as a result of court orders, 466 HHS employees for child support and alimony, 138 HHS employees for bankruptcies, and 5 HHS employees for Department of Education Indebtedness.

PRODUCTIVITY MEASUREMENT

Question: Madame Secretary, can you tell us whether you have a productivity measurement system within the Department and, if so, what percentage of your employees are covered by such a system?

Answer: The Department has measured quantitative and qualitative factors related to its productivity through the Operations Management System, a management-by-objectives system used over the last 12 years by Secretaries to set goals and track progress in critical areas. Through this system, the various departmental components set near term goals of 1 to 2 years, identify the steps they must take to achieve those goals, and regularly report their progress. While the system does track the procedural steps necessary to reach the goals (for example, establishing a policy position or publishing a regulation), the emphasis of the system has been on outcomes (such as, greater numbers of clients served, fewer cases of infectious disease occurring).

Different Secretaries have chosen to focus on different activities, but the overall result of the program has been to improve the delivery of services.

We have also put into effect the performance measurement requirements of the Civil Service Reform Act. Building on existing productivity standards, such as the numbers of claims to be processed per individual or the number of cases per investigator per year, we have established measureable goals for increasing our productivity.

In aggregate, we estimate that about 80 percent of the Department's employees are covered by work measurement systems.

The Social Security Administration, which administers the Old Age and Survivors Insurance, Disability Insurance, Supplemental Security Income, Aid to Families with Dependent Children and Black Lung entitlement programs, maintains a comprehensive work measurement system. The system covers about 75,000 employees, or 85 percent of the approximately 88,000 employees who administer these programs. Fifteen percent of the workforce is not directly measured but contribute to the product of the Agency -- for example, the Agency's computer programmers, the staff who oversee the district office operations in the field, and those who prepare operating instructions.

The Public Health Service (PHS) operates a variety of work measurement systems which cover a significant part of the workforce. While these systems cannot measure the quality of our research or service products, they do inform us of the workloads to be accomplished and the staffing required to perform these workloads.

Several other smaller units of the Department, including the Office of the Inspector General and the Office of the General Counsel, also maintain work measurement systems.

Question: Perhaps you could tell us now where you have had your greatest productivity increases and decreases and provide details for the hearing record.

Answer: I think two examples illustrate our attention to productivity and our achievements:

- o The Social Security Administration's Systems Modernization Plan

  Productivity in the Social Security Administration (SSA) has been increasing significantly in the recent past. For the years FY 1979 through FY 1981, productivity increased at a yearly average of over 3% (FY 1982 productivity data are currently being analyzed). These improvements are due, in part, to increased automation of various initial claims and post-entitlement actions and implementation of procedural changes to reduce administrative costs.

  Furthermore, SSA has undertaken a large, complex and very important effort to upgrade its outdated computer systems. One of our commitments in initiating this program is to increase the efficiency and effectiveness of the system, shorten processing times, and make our claims process much more accurate.

- o The Food and Drug Administration's Processing of New Drug Applications

  Over the past six years, the Department has worked hard to reduce the time the Food and Drug Administration takes to process new drug applications. Such a reduction is important not only to increase our productivity, but to make safe, tested drugs available to those who need them in the shortest time possible. So far we have been able to reduce our median processing time for drugs with important or modest potential effects by almost one third, from 17 months to 12 months.

Question: Do you have any plans to increase the number of employees who will be covered by your productivity measurement system in 1984 and if so, what is your new target?

Answer: SSA plans to increase the number of its employees covered by work measurement systems during the next year by extending work measurement to certain administrative areas where quantifiable counts can be obtained. SSA estimates that this

effort will raise the number of employees covered directly by work measurement to 90 percent of the work-force from the 85 percent currently covered.

CIVIL RIGHTS COMMISSION DATA REQUESTS

Question: Madame Secretary, as I'm sure you know, the Civil Rights Commission has been critical of the failure of Federal agencies and departments to honor Commission requests for information. An article in the March 14 Washington Times indicated that a Commission spokesman cited your Department as one of those agencies that had "delayed or refused information requests." Have you had an opportunity to look into this situation and, if so, can you tell us if the Department is taking corrective action?

Answer: After looking into this situation, I found that the Department did not delay or deny any information requested by the Commission. The Commission's latest request for information was forwarded to the Director of the Department's Office for Civil Rights on February 25, 1983. The Commission asked for information and documents needed for its annual review of Federal agencies having major civil rights enforcement responsibilities. The Office for Civil Rights replied to the request on March 14 and furnished all the requested information that was available. That Office did not, however, provide a copy of the "annual operating plan" since no such office-wide plan is required or developed. In addition, the Commission complained that the Department had not furnished a copy of a 1979 research report entitled, "The Capacity of State Agencies to Assist the HEW Office for Civil Rights." It turned out that the Commission did not in fact ask for this report in its original written request to the Department. The report focuses mainly on education matters and probably should have been directed to the Department of Education in any case. However, once the Department became aware of the Commission's desire to have a copy of this report, a copy was immediately made available to them.

EQUAL EMPLOYMENT IN HIGHER GRADES

Question: Can you tell us how the average GS grade for both women and minority employees at the Department compares with the average grade of their white male colleagues as well as the average grade as a whole?

Answer: The average GS grades for women and minority employees are 6.8 and 6.5 respectively, as compared to the average GS grade for white males of 9.2 and an overall average grade for the Department of 7.5.

Question: How many women and minorities occupy senior executive service and executive level positions at the Department both in absolute numbers and as a percentage of positions occupied?

Answer: As of March 1983, there are a total of 546 senior exeutive service and executive level positions filled. Of this total, 80 women and 48 are minorities, for percentage representations of 15 and 9, respectively.

Question: Give us an indication of how many women and minorities were promoted to positions at the GS-12 and above level during fiscal year 1982?

Answer: The number of women and minorities promoted to grades 12 and above during fiscal year 1982 were 1,127 and 495, respectively. The proportions of promotions going to women and minorities were 44 percent and 19 percent, respectively. This compares to their respective representation of 29 percent and 18 percent among the ranks of GS employees grade 12 and above.

Questions Submitted by Senator Mark O. Hatfield

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

Question: Nearly every day now the newspapers carry stories on what appears to be a new epidemic disease called AIDS. What is your view of the disease and what is the National Institute of Allergy and Infectious Diseases doing about it?

Answer: Acquired Immune Deficiency Syndrome (AIDS) is an apparently new infectious disease that results in a profound immune system breakdown. Because of the failure of the immune system, opportunistic infections are able to invade and some patients develop Kaposi's sarcoma. Over 1,300 patients have been diagnosed in the past three years. The mortality rate is high; no patient diagnosed as having AIDS more than two years ago is known to be living. The first cases were identified by scientists working with NIH supported grants and were reported in the medical literature of December of 1981. At about this same time, AIDS patients were being admitted to the NIH Clinical Center under a protocol for AIDS study. Scientists across the country became interested in this most interesting of new disesases and began adding AIDS research with funds from existing NIAID grants. In response to a Request for Applications (RFA) to study AIDS, the NIAID has now funded four meritorious research applications as a result of the RFA. NIAID-supported Sexually Transmitted Diseases Centers and Centers for Interdisciplinary Research in Immunologic Diseases continue to intensely study this disease. NIAID Intramural researchers are also actively studying various aspects of the Syndrome including attempts to identify a presumed infectious agent, epidemiological studies, and patient care and treatment. Ongoing studies supported by NIAID will total approximately $4,050,000 in FY 1983. The FY 1984 President's request would allow continuation of this research with additional studies in the search for an etiological agent. Total AIDS research studies are estimated to cost $6,050,000 in FY 1984.

Question: Can you do all the research that is necessary with the FY 1984 budget?

Answer: It is always possible to do more research, and Secretary Heckler has pledged that the Department will use whatever resources are necessary to find the answers on AIDS.

Current research could be expanded on the search for the infectious agent of this disease, the use of interferon and other substances for treatment of the basic immune defect in AIDS patients and the life-threatening complications, and other research begun to study immune abnormalities such as the increased production of immune globulins and high concentration of circulating immune complexes so typical of AIDS.

LYME ARTHRITIS

Question: In 1975, Lyme's Arthritis was first recognized in Lyme, Connecticut. I understand the National Institute of Allergy and Infectious Diseases has discovered the cause of this disease. Can you inform this committee of this recent development?

Answer: In 1982, Dr. Willy Burgdorfer and staff scientists from the NIAID Rocky Mountain Laboratories detected in ticks a spirochete that is now known to be the causative organism of Lyme disease. Epidemiologic evidence had pointed to ticks of the genus Ixodes as the vector of this disease. The scientists collected ticks from Shelter Island, N.Y. which is known to be a focus of Lyme disease. When they dissected the ticks they found the new spirochetes in more than half of them. Subsequent tests showed that laboratory rabbits developed skin lesions when fed upon by infected ticks and developed specific antibodies to the organism. Subsequently, the organism was grown in pure culture in the laboratory and shown to react with antibodies in the blood of patients who had recovered from the disease. Finally, within the last month two separate groups of investigators have reported in the New England Journal of Medicine the isolation of the same bacterium from patients with the disease. Working with these groups, Dr. Burgdorfer and other NIAID scientists report that the spirochetes have the same morphologic and immunologic features as the one islolated earlier from ticks. These findings now open the way to the development of appropriate prevention and treatment strategies.

DIABETES RESEARCH

Question: What is NIAID doing in diabetes research?

Answer: Diabetes related research of the NIAID includes studies on infections and immunogenetic factors that may induce diabetes, and studies related to the diagnosis and treatment of the disease. Typical NIAID studies involve viruses that are possible agents in the etiology of insulin-dependent diabetes, the immune response to bacterial and fungal infections that are frequent complications in patients with diabetes, and histocompatibility antigens and other host immunogenetic factors. The NIAID also supports developmental research on transplantation that serves as a basis for the recent effort to transplant pancreatic islet-cells on experimental animals.

During FY 1982, the NIAID supported 32 projects that were related to research in the field of diabetes. The funding level for this period amounted to $4,220,017.

BIOMEDICAL RESEARCH CAREERS IN ASTHMA AND OTHER ALLERGIC DISEASES

Question: We understand that there is a tremendous shortage of researchers and clinicians especially in the field of asthma and other allergic diseases. Would you tell us what the NIAID is doing to encourage bright young scientists to pursue biomedical research careers in this area?

Answer: The NIAID senses the need to make every effort to encourage bright young scientists to pursue biomedical research careers in this area through several awards, and training grants to universities. To bridge the period between fellowship training and independent investigator status, the Institute employs four mechanisms: Research Career Development Awards, Academic Awards, New Investigator Awards, and Clinical Investigator Awards. It is vitally important that we continue to support research career programs, which are designed to encourage young investigators to make a lifetime commitment to a field that has been underserved.

CLINICAL RESEARCH AND CLINICAL MEDICINE

Question: Both this year and in previous testimony, you emphasized the tremendous strides in the field of allergy and immunology. In your judgment, is there adequate support for clinical research and are the new developments being translated into clinical medicine?

Answer: There, indeed, is ever increasing evidence that recent tremendous strides in research in the fields of allergy and immunology have made the need for clinical research even greater. Many diseases are now known to be caused or aggravated by responses of the immune system. Some, such as allergy, immune deficiency diseases, autoimmune diseases, lymphomas, and organ transplant rejection, are almost exclusively problems in immunology. Many other ailments including chronic infections, hematologic disorders, and malignancies have important immunologic components. Research developments in allergy and immunology are being translated into clinical medicine; the entire November 26, 1982, issue of the Journal of the American Medical Association is entitled "Primer on Allergic and Immunologic Diseases" and consists of 21 "chapters" summarizing developments of importance to practicing physicians.

Important clinical research is carried out through NIAID funding of investigator-initiated grants, contracts, program project grants and centers. By nature, such research is very expensive and often long term. We can assure you that, within our mandated mission, our staff remains alert to promising research leads that show potential for clinical applicability. We are especially pleased with the interdisciplinary tenor of NIAID supported Asthma, Allergic, Immunmologic Disease Centers and the Transplantation Centers that especially focus on the work of the basic biomedical science components to the solution of problems of diagnosis, treatment, and prevention of allergic and immunologic disorders.

NATIONAL INSTITUTES OF HEALTH

Question: Last year the Committee asked for a report on the "Convent property" surrounding the NIH. Please summarize the report and conclusions. Do you view this property as important to the long-term growth and goals of the NIH?

Answer: Development of the NIH campus has been underway for almost five decades, following a gift of land by the Luke Wilson family in 1935. In 1948, 50 acres of the present NIH property were purchased from the Sisters of the Visitation in order to make possible the construction of the Clinical Center. At that time the remaining 11 acres, which is the site of a convent, were not acquired, but there was an informal understanding that eventually this property would be offered for sale as this 11-acre property is the only remaining privately owned land adjacent to the NIH campus. In October 1982, a decision was made to close the convent, relocate the remaining Sisters to other facilities, and offer the property for sale.

The convent property is currently on the market for $7.0 million. However, based on three independent professional appraisals, $4.2 million is considered a fair market price.

The convent property is located near the Warren G. Magnuson Clinical Center, which houses a 541-bed research hospital and the recently completed Ambulatory Care Research Facility. The Clinical Center serves as the hub of research on the NIH campus, with both laboratory and clinical research housed in close proximity.

NIH currently leases 460,000 square feet of office space and 18,000 square feet of laboratory space off the NIH campus. Accordingly, the convent building structure of about 40,000 gross square feet could be put to use, for example, to bring together research programs in such areas as the behavioral sciences and epidemiology. These research programs are currently occupying space either in office buildings off campus or converted chemical laboratories. Besides reducing leasing requirements, there are practical advantages in consolidating research programs on campus. For example, epidemiologists currently in off-campus rented facilities would benefit, in terms of operational convenience and reduced costs, from being closer to the clinical investigators with whom they work on designing protocols for clinical trials.

No resources are budgeted in FY 1983 and 1984 for the purpose of buying this property.

Questions Submitted by Senator Mark Andrews

COMMUNITY HEALTH CENTERS

Question: In your justification of appropriations estimates, it is stated that an intensive management review of community health centers has been undertaken to eliminate support for those which are less effective or which serve low priority areas. To this end, 284 projects have been defunded or are receiving only phase-out support.

How many community health centers are there that you would consider effective?

Answer: At the beginning of fiscal year (FY) 1983, 587 grantees received Federal funding to operate community health centers. Each of these programs was reviewed in FY 1982 and was found to have good management practices and be located in an area having a need for primary health services.

These programs will be reviewed again in FY 1983, on an individual anniversary basis, to determine whether they continue to meet nationally applied performance standards.

Question: How do you decide whether or not a community health center is effective, and what is considered a "high priority area?" My concern lies with the fact that North Dakota is a rural State--does this make it low priority?

Answer: As the program's primary objective is to develop the capacity to organize and deliver primary health services to unserved or underserved populations, all areas considered for funding are designated as medically underserved areas. Priority is further determined by the physician-to-population ratio, the percent of residents below the poverty level, the infant mortality rate and the percent of people above 65 years of age. Taken together, these criteria do not operate against rural areas.

Several objective standards are used to evaluate Bureau of Health Care Delivery and Assistance (BHCDA) supported primary care grantee performance at the service delivery level. These criteria include: a needs/demand assessment; health promotion/disease prevention activities; currency with Federal payback provisions associated with National Health Service Corps assignees; and clinical, administrative and financial management capabilities. Some of these criteria include standards which acknowledge the particular challenges in operating relatively small service sites in isolated rural areas.

Question: How do you intend to assure that the States take over the most effective and needed projects?

Answer: In preparation for the implementation of the Primary Care Block, BHCDA began a rigorous review of all community health centers in fiscal year 1982 to assure that the programs operated by the States under the block were effective and needed projects.

These reviews evaluate the fiscal, administrative, and clinical performance of the centers, as well as an assessment of the need for the centers' services in the areas.

A major change in the fiscal year 1983 funding criteria was the requirement that the centers solicit input from State and local officials concerning their views on the effectiveness and need for the centers.

We believe this arrangements for a review partnership with the involved State and local officials is an effective mechanism to assure the States they will be assuming responsibility for effective and needed projects under the Primary Care Block.

THE CARES PROJECT

Question: A program of particular concern to me is the CARES Project. This program is the Coordinated Ambulatory Rehabilitation Service and is an outreach project directed at giving medical care to chronically underserved rural areas in North Dakota. What funding level have you set for CARES for fiscal year 1984?

Answer: No funding level for fiscal year 1984 has been set for any of the primary care programs.

Question: How does the future look for the CARES project?

Answer: The CARES project was established to demonstrate how to develop local rural rehabilitation capability with the aid of a rehabilitation specialty hospital 400 miles away. The project has successfully demonstrated this concept in the southwest portion of the State and we are continuing to support the operational services provided by the project under the Community Health Centers program. Currently, CARES is expanding the demonstration to the northwest portion of the State and we are working with the project to develop continuing support for the second demonstration site through programs continued into the health block grants to the State.

Question: Has your department done any further research or studies regarding the efficiency of this type of program?

Answer: A February 1983 study of the project found that the CARES approach to developing local rehabilitation services for children and adults had been successful. The approach organizes local primary care physicians, a local hospital and non-physician rehabilitation providers into teams assisted by the University of North Dakota Medical Center Rehabilitation Hospital in Grand Forks. Patients receiving local services through this demonstration returned to family roles and lifestyle more rapidly, saved transportation costs and experienced reduced days of institutionalization.

Question: Also, could you comment on the rural health problem and what you are doing to try to meet this problem head-on?

Answer: Rural areas still experience disproportionate disability, poverty and shortages of health professionals compared with urban areas. While diffusion of physicians and past programmatic efforts have helped considerably, there are still rural areas that have great difficulty attracting physicians. This can be complicated by geographic isolation, inadequate transportation, environmental problems and lack of support services and professional backup.

Our primary care programs have always had a strong rural emphasis and we are working to strengthen these efforts. In 1982, of the 583 community health center grantees funded, 349 were in rural areas. We also are placing high priority on rural areas in the placement of National Health Service Corps providers, particularly if they are very isolated rural areas where physicians would not otherwise locate.

Question Submitted by Senator Arlen Specter

RUNAWAY AND HOMELESS YOUTH PROGRAM

Question: Several months ago, the Office of Management and Budget proposed to set aside $8 million of the $21.5 million appropriated for the Runaway and Homeless Youth Act (RHYA) in the form of a state block grant program. It is my understanding that the Office of the General Counsel in the Department of Health and Human Services found this proposal to be counter to the intent of Congress, and hence illegal. Would you kindly submit for the record a copy of the statement prepared by the General Counsel. Please submit as well any plans you may have for allocating FY 84 RHYA funds.

Answer: Following a review of the Runaway and Homeless Youth Act, the Department's Office of the General Counsel (OGC) indicated that limiting the grant competition to State applicants or giving priority to State applicants over private entities that could demonstrate experience in dealing with runaway youth appeared to be inconsistent with the priorities specified in the Act.

Based on its review, the Office of the General Counsel concluded that while a State applicant can qualify for priority treatment under Section 5713 (either because its application requested a grant of less than $150,000, or because of its demonstrated experience in providing services to runaway and homeless youth and their families) such priority could not be given based solely on the applicant's status as a State, nor would it be consistent with the requirements of Section 5711 (a) to exclude from consideration private organizations with prior experience in serving runaway youth.

FUNDING ALLOCATION IN FISCAL YEAR 1984

In Fiscal Year 1984 the appropriation level requested for this program is $10,514,000. Of this amount approximately $10,200,000 will be allocated through the statutory formula for the support of Runaway and Homeless Youth Centers. About $300,000 will be devoted to the National Communications System operations. With the $10,200,000 we expect to provide support to approximately 170 Centers serving about 45,000 runaway or homeless youth. The Hot Line will serve 300,000 youth and their families.

Question Submitted by Senator Daniel K. Inouye

NATIONAL INSTITUTE OF DENTAL RESEARCH

Question: I understand that the Institute of Dental Research has undertaken an effort to modify our Nation's diet in order to significantly decrease our current consumption of sugar. I further understand that this initiative is of an on-going nature, and to date has not been successful nor is significant success expected in the foreseeable future. Accordingly, I would

appreciate learning why in these economic hard times does the Institute continue to spend money on projects that do not seem to be fruitful. Your clarification of this would be appreciated.

Answer: Since dietary factors play a significant role in the causation of dental caries, it is essential that the National Institute of Dental Research continue its research efforts to find the means to modulate and reduce this risk. Sugar content, frequency of consumption, and consistency are among the dietary factors that contribute to cariogenicity. The Institute has made significant progress in developing a reliable animal model for ranking common food types according to cariogenic potential and currently has underway a large epidemiological study of children's snacking patterns to further identify risks.

Questions Submitted by Senator Lawton Chiles

REFUGEE AND ENTRANT PROGRAM FUNDING FOR FLORIDA

Question: In the justification of appropriations requests for refugee and entrant programs, there is a breakdown of how much cash each State could expect to receive under the Administration's proposals for FY 1984, compared to 1982 and the 1983 estimate. That chart shows Florida receiving a little over $11 million in FY 1983, dropping to $9.5 million in FY 1984. What programs do these figures include? For instance, the 1983 estimate could not possibly include the $31 million in targeted assistance the State has been appropriated for FY 1983, nor the $5 million education aid to Dade County.

Answer: Given the 36-month statutory limitation on entrant and refugee eligiblity, it was necessary for purposes of budget formulation to distribute, on a national basis, FY 1983 and 1984 appropriations expressed as a percentage of each State's actual refugee program expenditures in FY 1982. The summary table should not be interpreted as what any given State could expect to receive on behalf of its actual eligible refugee and entrant populations in those fiscal years.

For example, in the case of Florida, with a significant entrant rather than refugee population, the State can expect to receive approximately $26.5 million for refugee and entrant cash and medical assistance and social services. The summary table's FY 1983 estimate for Florida of $11.3 million only represents the State's estimate expressed as a percentage of its actual FY 1982 refugee program costs. The State can expect to receive full reimbursement for services and assistance provided on behalf of eligible refugees and entrants in FY 1983 and 1984.

Question: Could you provide a breakdown of just how much Florida is to get under the Administration's proposals for each refugee and entrant assistance program?

Answer: For FY 1983 the State of Florida can expect to receive Federal funding for refugee/entrant assistance as follows:

State Administered Program of Domestic Assistance (Cash and medical assistance, unaccompanied minors)	$16,000,000
Social Services	10,502,710
Targeted Assistance	[pending]
Entrant Education Assistance for Children	5,000,000
Refugee Education Assistance for Children	[pending]

For FY 1984, the State will receive a Federal grant award based upon its eligible refugee/entrant populations to meet the State's share of costs under AFDC, Medicaid, SSI and State and local general assistance. This award will also include costs for State administration and its unaccompanied minors program. In addition, the State will be eligible for Federal assistance on a per capita basis for purposes of providing cash and medical assistance to noncategorically related refugees and/or any special needs of its eligible refugee population.

Question: What is the status of refugee and entrant assistance payments to the State of Florida for FY 1983?

Answer: Based upon the State's estimated eligible refugee/entrant population, the State has been awarded Federal funding through the third quarter of FY 1983, the following:

State Administered Program (cash and medical assistance)	$12,050,000
Social Services	$ 9,760,710
Targeted Assistance	[pending]
Entrant Education Assistance for Children	$ 5,000,000
Refugee Education Assistance for Children	[pending]

TARGETED ASSISTANCE GUIDELINES AND REGULATIONS

Question: Have all the necessary regulations and guidelines been issued for release of funds?

Answer: A proposed notice for the Federal Register has been prepared by the Office of Refugee Resettlement and is currently under review. We expect to publish it in the near future.

TIME SCHEDULE FOR REFUGEE AND ENTRANT AWARDS

Question: What is the anticipated timetable for release of the targeted assistance, education impact aid, social services funds, etc.?

Answer: Federal targeted assistance in the amount of $30 million will be released in the third quarter of FY 1983 based upon applications submitted by the States. An additional $40 million will be made available for targeted assistance in the fourth quarter of the fiscal year.

For purposes of educational impact aid for the 1983-1984 school year, $5 million has been transferred to the Department of Education for release in mid-May and an additional $16.6 million will be made available in the fourth quarter of FY 1983.

Federal social services funding has been released to the States, on a quarterly basis, through the third quarter of 1983 to meet 75 percent of the State fiscal year planning figures. The remaining 25 percent will be made available in the fourth quarter of FY 1983.

Question: Is the Department on schedule for cash-medical reimbursement?

Answer: Quarterly grant awards have been issued to all States and jurisdictions participating under the program through the third quarter of FY 1983 and the Department does not anticipate any problems in the issuance of fourth quarter awards on a timely basis.

BLOCK GRANTS

Question: You propose adding migrant health, family planning, and black lung programs to the Primary Care Block Grant. Yet you would level fund the primary care block, with no additional request to cover the $165.5 million that is being spent on migrant, family planning, and black lung services.

Similarly, your budget proposes elimination of all funds for Community Services Block Grants, with only a $50 million increase in the social service block that is supposed to "pick up" these activities.

How do you expect hard-pressed States and local agencies, that have already faced significant revenue loses, to make up the difference in these new Federal funding cuts?

Answer: First of all, our proposal to include migrant health, family planning and black lung clinics programs into the Primary Care Block Grant does fund all programs at the FY 1983 Continuing Resolution (CR) levels. The FY 1983 CR provided $295 million for the Community Health Centers program and $165 million for the remaining three programs, as you mentioned. This totals $460 million, the same level as requested in the President's FY 1984 budget for the expanded Primary Care Block Grant.

Secondly, we realize that the $50 million increase in the Social Services Block Grant (SSBG) is not sufficient to cover all of the activities previously funded under the Community Services Block Grant (CSBG). Nor was it our intention to do so. We decided not to request separate funding for the CSBG for several reasons.

CSBG funded activities overlap, in large measure, activities that can or are being funded under other programs, the SSBG being one. Under our proposal, States can elect to continue funding effective programs and discontinue marginally or ineffective programs.

States will have increased flexibility in developing a rational, coherent service delivery system without two different sets of regulations and requirements.

Community Action Agencies will remain eligible for funding under the Social Services Block Grant, under which many already receive funding.

Question:

You are proposing elimination of funds for health planning and utilization review under the PSRO program. Although Congress has passed the prospective reimbursement plan for hospitals, the Administration has yet to submit comprehensive "competition" proposals for curtailing the cost of health care, particularly in the Medicare and Medicaid programs.

How do you expect us to move forward in cost containment, when the Administration proposes to eliminate the only two programs, besides prospective reimbursement, that we have in place to constrain costs?

Answer:

The Administration proposes zero funding for Professional Standards Review Organizations (PSROs), because they have failed to slow the rise in health care costs and they represent excessive government regulation. Length-of-stay reviews, which were performed by PSROs, will no longer be necessary because the Medicare prospective payment system for hospitals will provide hospitals with the financial incentives to control excessive utilization without government intervention. Other quality control functions, such as assuring the appropriateness of an admission and the accuracy of the data for billing purposes, can be performed at less expense by Medicare contractors. The contractors can integrate these responsibilities into their ongoing claims processing activities.

The Administration opposes health planning because it erects artificial barriers that inhibit free market entry into the health care industry, which is counter to the Administration's policy to promote effective functioning of private market forces. Health planning was doomed to fail because it attempted to restrain health care costs without altering the health care financing system, which is the main reason for these rising costs. Research on the effects of health planning has been conducted by several analysts and has consistently shown that health planning, in the form of certificate-of-need regulation, has not been effective in restraining hospital per diem, per case, or per capita costs.

The Administration's Health Incentives Reform Package would remove the need for PSROs and health planning programs. Instead of merely capping health care expenditures, the Administration's proposals attack the real problem of rising costs -- the perverse incentives in the financing system. Cost-plus reimbursement, badly-structured cost-sharing, and open-ended tax subsidies underlie health care inefficiency. The Health Incentives Reform Package addresses each of these issues, while calling on all parts of the health care market -- providers, consumers, hospitals -- to share in the responsibility of cost containment.

HEALTH PROFESSIONS

Question: The HHS budget includes significant cuts for family practice, general dentistry programs, and for advanced nurse training, nursing research, and similar programs. In light of the positive impact these programs have on the cost, quality, and availability of health care, how do you justify the cuts?

Answer: The 1984 request emphasizes the policies and program priorities of this Administration, with the overall goal of improving the health status of the U.S. population. The Health Professions budget is directed at providing sufficient health manpower in geographically underserved areas, sufficient primary care personnel and at improving the skills of health practitioners in methods of health promotion disease prevention.

Question: Does this mean that increases in primary care physicians equal our geographic and numerical shortages, and that the problems of retention and shortages of nurses with advanced training are solved?

Answer: The supply of primary care physicians is projected to be in balance to the requirements in 1990. The continued funding of the family medicine residencies and training program should improve the accessibility of comprehensive primary medical services for all U.S. citizens. There is an acknowledged problem, recently confirmed in the Institute of Medicine Report, with shortages of nurses in certain work settings and locations, such as hospitals versus doctors' offices, industry or teaching facilities, or rural areas, and on the evening or night shifts in demanding specialties such as intensive care units. Increasing the supply of nurses is not likely to solve these structural problems. The 1984 budget provides selective support of those nurse training programs with the highest national priority.

SUBCOMMITTEE RECESS

Senator WEICKER. The subcommittee will now stand recessed until 8:30 tomorrow when we meet in this room to hear the budgets of the Health Resources and Services Administration and the Assistant Secretary for Health.

[Whereupon, at 10:10 a.m., Tuesday, April 5, the subcommittee was recessed, to reconvene at 8:30 a.m., Wednesday, April 6.]

18-040 O - 83 - 7

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1984

WEDNESDAY, APRIL 6, 1983

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, D.C.

The subcommittee met at 8:30 a.m., in room SD-116, Dirksen Senate Office Building, Hon. Lowell P. Weicker, Jr. (chairman) presiding.

Present: Senators Weicker and Burdick.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HEALTH RESOURCES AND SERVICES ADMINISTRATION

STATEMENT OF DR. ROBERT GRAHAM, ADMINISTRATOR

ACCOMPANIED BY:
JOHN H. KELSO, DEPUTY ADMINISTRATOR
DR. JAMES A. WALSH, ASSOCIATE ADMINISTRATOR
ANTHONY L. ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET, DHHS

BUDGET REQUEST

Senator WEICKER. Good morning. The hearing will come to order.

Today, we will hear from the Health Resources and Services Administration in the Department of HHS.

The Health Resources and Services Administration was created last year by combining the old Health Resources and Health Services Administrations, putting together activities relating to the delivery of health care to underserved groups, and training of health professionals in critical areas.

The portion of the new agency which falls under this subcommittee's jurisdiction has a work force of more than 4,400 and a budget exceeding $1.2 billion.

But just as the Health Resources and Services Administration is getting off the ground, the administration proposes program shifts, consolidations, and cuts that would reduce its budget by about $1 billion. The fiscal 1984 budget request also proposes to abolish 639 staff positions as the result of these program changes.

Here to present the budget proposals is Dr. Robert Graham, the agency Administrator.

We welcome you, Dr. Graham to this committee's hearing. You may proceed with your statement.

PREPARED STATEMENT

The statement in its entirety will be included in the record.

And you might introduce those at the table who accompany you.

[The statement follows:]

STATEMENT OF ROBERT GRAHAM

I appreciate this opportunity to appear before you today to discuss the fiscal year 1984 budget request for the Health Resources and Services Administration. As you are aware, Mr. Chairman, this budget excludes the Indian Health Service, which is reviewed by the Department of the Interior and Related Agencies Subcommittee.

The Health Resources and Services Administration was established on September 1, 1982 with the merger of the Health Resources Adminstration, the Health Services Administration, and the Health Maintenance Organizations program which had previously been part of the Office of the Assistant Secretary for Health.

The fiscal year 1984 budget request for Health Resources and Services is $324,444,000 and 3,306 positions. Included in this request are funds to continue the efforts of the National Health Service Corps; manage the National Hansen's Disease Center and provide for the Federal payment to Hawaii for treatment of persons with Hansen's disease; and operate the Federal Employee Occupational Health program. Also included in this request are monies to administer the Health Professions portion of the Omnibus Budget Reconciliation Act of 1981, which extended the Health Professions and Nursing authorities through 1984. Funds also are provided to continue monitoring the Medical Facilities and Health Maintenance Organization loan portfolios, as well as other activities involving health facilities and Health Maintenance Organizations.

Health Care Delivery and Assistance

The 1984 budget request of $96,046,000 for the National Health Service Corps will support a field strength of 1,989 Federal salaried assignees. The NHSC will continue to focus on identification of highest need communities as it helps to place health professionals in Health Manpower Shortage Areas. Federal assignees will be utilized especially in meeting the requirements of such localities. Other practitioners who are obligated to serve in the NHSC are fulfilling their obligations under the private practice option (PPO). In 1984, 500 scholarship recipients are expected to elect the PPO; and 80 recipients, currently serving in the Corps, are expected to convert to the PPO, bringing the total number of scholars fulfilling their obligations under this option to approximately 1,300 out of a total combined field strength of 3,283. Because individuals electing the PPO receive no direct Federal salary support, the PPO furthers the goals of the NHSC at less expense to the Federal Government.

The budget request includes $18,183,000 for the continuation of patient care, medical education and research activities at the National Hansen's Disease Center; for Hansen's Disease contract patient care; and for payments to survivors and dependents of the Tuskegee Syphilis Study. While the budget proposed for the National Hansen's Disease Center is slightly below the FY 1983 dollar level, the committee can be assured of our commitment to maintain the quality of care that is now provided. This savings can be accommodated by reductions in nonpersonnel related expenditures except where personnel expenditures can be lowered without diminishing the quality of patient care. Also requested is

$1,905,000 for payments to the State of Hawaii to partially support the cost and treatment of persons with Hansen's Disease; $1,194,000 to maintain the Federal Employee Occupational Health program; $20,091,000 to manage and operate these programs; and $883,000 for routine maintenance and repairs and to construct a covered walkway at the National Hansen's Disease Center in Carville.

The total budget request for these programs is $138,302,000 and 2,655 positions.

Health Professions

The 1984 request for health professions education activities is 116,506,000 for grant and contract programs, and $12,527,000 and 258 positions for direct operations. The budget request also proposes to authorize $175,000,000 for loan guarantees made under the Health Education Assistance Loan program. This will bring the contingent liability of this program to over $628 million.

This budget continues Administration policy to focus the Federal role in health professions education on the eight objectives contained in the Omnibus Reconciliation Act of 1981.

The first objective of promoting a sufficient supply of primary care professionals is addressed in 1984 by highly targeted support to specialty training and residency programs in family medicine, general internal medicine and pediatrics, and development of family medicine departments in institutions training medical personnel.

The second major objective is to fund specialized programs that help assure the availability of health professionals in underserved areas. A major program directed at this objective is the Area Health Education Center (AHEC) program, which provides remote site training for medical and other health professions students in medically underserved areas; and improves coordination with existing resources, including institutions, within these areas. The funding request for the nurse practitioner and physician assistant programs also contributes toward achieving this objective, since studies show that the majority of these practitioners tend to locate in such shortage areas. Special initiatives in remote site training, podiatry, and continuing education also will enhance the availability of health professionals in shortage areas.

A third major objective is to aid disadvantaged individuals in choosing and pursuing a health professions career. Continued funding for the disadvantaged assistance program in 1984 will emphasize involving the health professions schools in coordinating efforts to enlarge the minority applicant pool and to foster, among these schools, a commitment to increasing minority enrollments. Support of the financial distress program in 1984 will preserve National resources for training minorities in health professions disciplines.

The fourth major objective is in the area of nursing. The Institute of Medicine Study on Nurse Education, recently submitted to Congress, concludes that the aggregate supply of nurses is in balance; however, this report found that there are still shortages of certain kinds of nurses and that maldistribution problems still exist. The 1984 budget request will provide support to assist training institutions and hospitals in developing innovative solutions to improve the utilization and distribution of nurses and to increase the number of

nurses providing bedside care. The fifth objective is to promote National health care priorities through the development and implementation of targeted special projects. The 1984 budget request continues support for high priority health professions special education initiatives which address both current and emerging health problems. This program will support programs which train students to function effectively and efficiently as members of a health care delivery team. High priority initiatives include: maximizing independence and mobility of the elderly in long term care institutions and training of health care personnel in new concepts of geriatrics; support of veterinarian medicine special projects; and other important areas, including developing innovative techniques to help meet the needs of high risk target groups, especially children and pregnant women, and emphasizing primary care and prevention.

The sixth major objective is to support programs that address the area of health promotion and disease prevention. Programs in public health will provide support in this area. Also, the preventive medicine residencies program will develop a cadre of preventive specialists needed to provide more general health care for the people. Finally, the special educational initiatives projects for allied health will address training in disease prevention and health promotion.

The seventh major objective is to continue the program of health professions analysis and reports. The intent is to provide accurate and timely information on the Nation's health professions supply, distribution and requirements, to permit the development and evaluation of sound National health policies. This is an intramural, labor-intensive program which identifies geographic and specialty distribution problems, designates health manpower shortage areas, and conducts the targeted analyses needed to answer significant questions associated with current and anticipated health policy issues.

The eighth major objective is to promote effective "debt management" activities of the health professions and nursing student loan programs. Efforts will be made to reduce the loan delinquency rate at health professions and nurse training institutions by improving efficiency and effectiveness in debt collection activities for funds owed the Federal Government from previous student borrowers.

The total budget request for the health professions program is $129,033,000 and 258 positions.

Health Maintenance Organizations and Resources Development

The budget request for the Health Maintenance Organizations and Resources Development programs is $46,327,000 and 231 positions.

In fiscal year 1984, $14,327,000 will be used to (1) to monitor outstanding health facility loans and loan guarantees in order to minimize Federal default liability; (2) to monitor health facility construction grants, recovering Federal funds where required; (3) to ensure that those facilities that previously received Federal funding comply with requirements to provide a reasonable level of uncompensated care to persons unable to pay; (4) to monitor outstanding Health Maintenance Organization loans and loan guarantees in order to minimize Federal default liability; (5) to provide technical assistance to developing and operating Health Maintenance Organizations; (6) to identify private sector financing needed to

accomplish future development and growth of HMO's; (7) to evaluate HMO's to determine whether they meet all requirements for Federal qualification; (8) to monitor all qualified HMO's, including those with Federal loans and loan guarantees, to assure continued compliance with all Federal regulatory requirements; (9) to assist in the development of Department policy in the area of health facility planning and capital formation; (10) to administer a program designed to promote energy conservation and cost savings by health facilities; and (11) to pay interest subsidies on construction loans for four health professions teaching facilities. In addition, $32,000,000 is available to pay interest subsidies on guaranteed loans made from the Medical Facilities Guarantee and Loan Fund.

No funds are requested for the Health Planning program, consistent with the President's intent to reduce regulatory burdens on the States, eliminate ineffective programs, and to permit them greater flexibility in administering programs within their State.

Program Management

The Program Management request for $10,782,000 and 162 positions provides funds for the Office of the HRSA Administrator. This office provides leadership and support for a variety of agency wide management and support functions including short and long-range program planning, evaluation, and policy coordination; management of personnel; financial management; procurement; and management systems.

Thank you for providing me with the opportunity to summarize the Health Resources and Services Administration budget request. Mr. Chairman and members of the Committee, I will be pleased to answer any questions you may have on the specifics of this budget request.

Biography of Robert Graham

NAME : Robert Graham

BIRTHPLACE : Pueblo, Colorado

DATE OF BIRTH: FEBRUARY 15, 1943

EDUCATION : Earlham College, Richmond, Indiana; A.B. Degree, 1965

University of Kansas School of Medicine; M.D. Degree
1970

Resident in Family Practice, Baptist Memorial Hospital, Kansas City, Missouri, 1974-1975

PROFESSIONAL ACTIVITIES

1. September 1982 - Present
Administrator, Health Resources and Services Administration, Department of Health and Human Services

2. January 1981 - August 1982
Acting Administrator, Health Resources Administration, Department of Health and Human Services

3. July 1979 - December 1980
Professional Staff Member, Subcommittee on Health and Scientific Research, Committee on Labor and Human Services, United States Senate

4. July 1978 - 1979
Deputy Administrator, Health Resources Administration, Department of Health Education and Welfare, and

Executive Secretary, Graduate Medical Education National Advisory Committee (GEMANAC)

5. July 1976 - July 1978
Deputy Director, Bureau of Health Manpower, Health Resources Administration, Department of Health Education and Welfare

6. January 1976 - June 1976
On staff of Program for Health Management, Baylor College of Medicine, Houston, Texas, and

Instructor, Department of Community Medicine, Baylor College of Medicine, Houston, Texas

7. February 1973 - January 1976
Assistant Director, Division of Education, American Academy of Family Physicians, Kansas City, Missouri, and

Administrative Officer, Society of Teachers of Family Medicine

8. June 1970 - February 1973
Assistant Administrator for Agency Goals, Health Services and Mental Health Administration, Department of Health Education and Welfare, Washington, D.C.

9. 1970-1973; 1976-Present
Commissioned Officer, Active Duty, United States Public Health Service; Assistant Surgeon General, September 1982 -

APPOINTMENTS

1. Member, National Board of Medical Examiners (Federal Representative), 1981-1982

2. Consultant, National Academy of Sciences/Institute of Medicine, Social Security Studies, 1974-1976

3. Advisor, Robert Wood Johnson Foundation, Rural Practice Project, 1975-1979

4. Consultant, Bureau of Health Manpower, Office of the Director, 1975-1976

5. Consultant, National Health Service Corps, Office of the Director, 1973-1974

6. Consultant, Study on the Place of Behavioral Sciences in Schools of Medicine, 1969-1970

7. Student Consultant, Carnegie Commission on Higher Education, 1969-1970

ASSOCIATIONS

1. American Academy of Family Physicians, 1973 -

2. American Medical Association, 1970 -

3. Association of American Medical Colleges, 1968 -

4. Society of Teachers of Family Medicine, 1973 -

5. Society for Health and Human Values, 1969 -
(Member, Executive Council, 1971-1975)

RECENT PUBLICATIONS

1. "Political and Legislative Influences on Primary Care"; Banta, H.D., Graham, R. ; The Mount Sinai Journal of Medicine,Vol. 45, No. 5, Sept.-Oct. 1978

2. "Public Policy Implications of Graduate Follow-Up Studies in Family Practice" ; Graham, R. , The Journal of Family Practice, Vol. 11, No. 5, Oct. 1980

3. "Funding Issues in Primary Care and Family Practice: A Policy Perspective" , Graham, R. , and Lawton, S. , The Journal of Family Practice, Vol. 13, No. 4, Sept. 1981

PERSONAL INFORMATION

Spouse: Jane E. Henney, M.D.

INTRODUCTION OF ASSOCIATES

Dr. GRAHAM. To my right, Mr. Chairman, is Mr. Anthony Itteilag who is the Deputy Assistant Secretary of the Budget for the Department of Health and Human Services.

To my left is Dr. James Walsh, the Associate Administrator for Operations and Management.

To his left is Mr. John Kelso who is the agency's Deputy Administrator and prior to that was the Acting Administrator of the Health Services Administration.

Also with me this morning, immediately back of me, are the three Bureau Directors, if I could introduce them, because I may ask them to respond to some of your questions: Mr. Tom Hatch, who is the Director of the Bureau of Health Professions; Dr. Edward Martin, Director of the Bureau of Health Care Delivery and Assistance; and Dr. Daniel Whiteside, Director of the Bureau of Health Maintenance Organizations and Resources Development.

Since the full opening statement will be submitted for the record, let me simply summarize.

Senator WEICKER. Excuse me just a minute.

All those standing outside please come in and sit down; there are plenty of seats.

I beg your pardon go right ahead.

Dr. GRAHAM. That's fine.

It is a pleasure to have the opportunity to present the first HRSA budget to you and to describe the activities for the agency that we propose for fiscal year 1984.

The President's budget provides for the continuation of our efforts through the National Health Service Corps, National Hansen's Disease Center, and for the creation of the primary care block grant program. It will allow us to continue our responsibilities in the Bureau of Health Professions in supporting the highest priority health professions development programs; also to allow us to continue to monitor Health Facilities and Health Maintenance Organizations' activities.

With that very quick overview and summary, I and the staff here would be happy to respond to any questions that you have, sir.

CURRENT LAW

Senator WEICKER. Your budget justification on page 68 states: "The President's appropriations request of $292,444,000 for this account includes current law adjusted by a net decrease of $18,942,000."

The term "current law" is one with which we are quite familiar since it is widely accepted as the current enacted appropriations level.

Apparently, your definition is something quite different. By our accounting, the 1983 continuing resolution provided $1,310,526,000 for the programs and activities under health services and health resources.

Do you agree with this appropriation?

Dr. GRAHAM. I believe, if I may ask Mr. Itteilag, the use of the term "current law" in that context is the President's 1983 budget proposal—

and that would be the difference between the 1983 proposal and the 1983 continuing resolution?

PROPOSED TRANSFERS TO OASH

Mr. ITTEILAG. Mr. Chairman, you are correct in citing the fiscal year 1983 continuing resolution amount for this account. The budget does propose, and is the reason that the figures are so dramatically different between this and 1984, that several transfers be made which affect this account—most prominently that of shifting the maternal and child health block grant to the account of the Office of the Assistant Secretary for Health and transferring certain primary care programs and proposing to fund them as a block grant also in the account of the Assistant Secretary for Health.

Senator WEICKER. Well, that is not current law, is it?

Mr. ITTEILAG. Mr. Chairman, with respect to the maternal and child health block grant, there is nothing in the current legislation that requires us to administer it within this account as compared to the Office of the Assistant Secretary for Health account.

With respect to primary care, it is correct that the proposed block grant of what are now categorical programs requires a change in legislation. And so it could not be characterized as current law.

CURRENT LAW

Senator WEICKER. Why don't the counsel, Gar Kaganowich and Claudia Ingram, indicate exactly to you what they are indicating to me, because we are going to have a problem here. I am just taking over this committee, and I want to make sure we set the parameters. I expect we are all going to be around for a few years. I would like for them to make comments to you that they just made to me.

Ms. INGRAM. Even after you account for all of the program deductions, the comparable 1983 program level is $483.9 million; roughly, compared to $292.4 million in this year's budget proposal. What you have is a budget presentation which calls for current law or which is indicated as being current law, but which has included about $191 million in real program reductions.

And from the standpoint of the congressional budget presentation, that is not current law. Those are not comparable budgets.

Mr. KAGANOWICH. The other problem is that you can't arbitrarily transfer these block grants into the Office of the Assistant Secretary for Health without the approval of this committee. It would require us to physically move the legislation from one account to another, and this committee has not done that in the past.

So the references to current law are unclear at best.

Dr. GRAHAM. Let me say—because I don't know how much of this is a HRSA issue versus a departmentalwide issue—I agree with the chairman. I think it is very important that we get the semantic base straightened out first.

For my understanding, your reference to current law would be what base?

Mr. KAGANOWICH. The 1983 appropriation.

Dr. GRAHAM. Does appropriation mean continuing resolution?

Ms. INGRAM. That's right. That's the definition which we have worked under now since really 1976 with the enactment of the Budget Act.

Dr. GRAHAM. It seems to me that this type of issue has come up every year, and that is because of the action of the Congress in not passing the CR until December, when the final fiscal year 1984 budget preparation was just leaving the Department.

I don't believe that this is the first year that reference to current law has been potentially out of sync with the latest enacted congressional appropriation, is it?

Last year, we were on a CR the entire year.

Mr. KAGANOWICH. You can't use current law. It is apples and oranges, Mr. Administrator.

Dr. GRAHAM. I understand that.

Mr. KAGANOWICH. And you can't use current law in reference to a $324 million budget when, in fact, the budget is basically $1.3 billion when you combine the two agencies.

Dr. GRAHAM. Maybe I better keep out of it because it is your department.

Mr. ITTEILAG. Let me try just a little bit further.

Senator WEICKER. Well, I think the point has been established that we can't track this kind of a budgetary process. I made the point as to where I think the discrepancies are, as well as the staff, and I understand the point you are making.

I also have learned about this problem, in your Department and other departments—I understand what it is the administration is trying to do, but now there is no point in my beating the ceiling with you people again. We have to get this thing worked out so that we can all conduct these hearings in a way that makes sense to everyone.

I would suggest that we will work with you on this as best we can, but I would suggest that in the future the staffs work together so we are talking about the same thing across this table.

Believe me, I am not interested in the hopes of the Department or of any segment of the Department so far as the law and the budget are concerned. I only deal with what the law is. I have repeated this time and time again to everybody that has come before us.

Both in terms of my legal responsibilities, constitutional responsibilities, and in terms of just solid fiscal practice, what people's speculations and hopes and all the rest of it are is not material to this chairman. It is always nice to know what you have in mind, but really, that is more the province of the authorizing committee and not the Appropriations Committee.

My scope is very narrow. It deals with the dollars and cents. In any event, from the budgetary point of view, let's get this type of groundwork set so that we don't have to jump all over the place, which is

what we are going to be doing here on the basis of the way the presentation has been made.

FUNDING FOR DISCRETIONARY PROGRAMS

Mr. ITTEILAG. I think, Mr. Chairman, though, there are important points to be made on behalf of the administration's proposal. One is that it is possible to propose within current law decreases or deletions of funding for discretionary programs.

For example, it does not require any change in the law for the administration to propose zero funding for the health planning program.

Now, it is entirely possible that the Congress will not agree with that, but at least we can propose it.

Second, it is also legitimate in my view for the administration to propose shifting a program from one account to another account as long as the basic legislation does not require that program to be budgeted, for example, in this particular appropriation.

And again, we present it. We will give our views and our justifications for that. And the Congress can take whatever action it thinks appropriate.

Senator WEICKER. Then, let me ask the question: In your budget presentation, will any of the matters raised in your fiscal presentation require legislation?

Mr. ITTEILAG. Yes, Mr. Chairman.

Senator WEICKER. That's the whole problem here. How am I going to bounce around from one to the other? I am not disputing what it is you can do, but you have an element of what you can't do without the Congress in here all at the same time.

Mr. ITTEILAG. We have an element of what we can't do under current law and what traditionally the Appropriations' Committees both in this body and in the other body have not been willing to do; you are entirely correct, Mr. Chairman.

Dr. GRAHAM. I believe, in the budget presented to the committee, that any proposals we have made for fiscal 1984 that require a change in the statute are clearly noted as requiring such change.

REDUCTION IN 1984 STAFFING LEVEL

Senator WEICKER. You propose to do some heavy slashing of positions in the fiscal 1984 budget. It appears under your request some 639 positions would be abolished from the 1983 staffing level of about 4,400. The biggest cut of about 435 positions would result from changes in your two block grants, primary care and maternal and child health.

Would you please confirm these figures?

And then, would you please explain these substantial cuts?

And last, if Congress rejects these proposals, what would it cost to put these positions back in the budget?

Dr. GRAHAM. First, your figures are correct, 435 is the correct aggregate number that would result from proposed changes in the Bureau of Health Care Delivery and Assistance portion of the budget.

The reason for those changes is that as you move to a block grant approach as proposed, it is not necessary to have the same level of personnel on the Federal payroll to carry out block grants as you have in monitoring the types of activities that we presently have under community health centers, migrant, black lung, and the 15-percent set-aside for maternal and child health projects. That total is roughly 435 individuals who would no longer be Federal employees as these programs move to the block grant status.

If you wish, we can supply for the record the correct amount that would be necessary to maintain those programs at the current services' level if the Congress does not concur with all the parts of this proposal.

[The information follows:]

The following summarizes the impact on the Health Resources and Services Administration and on the Office of the Assistant Secretary for Health accounts of restoring the primary care categorical programs and the MCH block grant as they exist under current law to the Health Resources and Services Administration in 1984:

	1983 continuing resolution		1984 President's budget		1984 current services	
	Positions	Dollars	Positions	Dollars	Positions	Dollars
Bureau of Health Care Delivery and Assistance, direct operations	[1]739	[1]$38,351	343	$20,091	707	$37,471
Program management	217	16,681	162	10,782	217	17,459
(Categorical programs and MCH block grant)	(45)	(2,600)			(45)	(2,722)
Family planning			([2])	([2])	66	3,498
OASH primary care and MCH block grant direct operations	40	2,060	40	2,060		

[1] Includes 66 positions and associated support dollars for family planning.
[2] In OASH proposed primary care block grant.

The 1984 current services level for BHCDA direct operations: Excludes 66 positions and $3,498,000 required for the family planning activity which has been transferred to the Office of the Assistant Secretary for Health; includes positions and funds from the OASH block grant for total restoration of 370 positions associated with primary care categorical programs and MCH block grant 15 percent set-aside provision and mandatory increases associated with the 370 positions; excludes 6 positions and $278,000 associated with reduced activity for NHSC scholarship program.

The 1984 current services level for the program management activity; includes 55 positions and support dollars and mandatory increases for HRSA overall agency management of primary care categorical programs (35 positions and $2,117,000); of MCH block grant and 15 percent set-aside (10 positions and $605,000); and of Bureau of Health Professions and Health Planning activities, 35 other-than-permanent work-years, and other costs such as centralized payments (10 positions and $3,955,000).

DIRECT OPERATIONS RESOURCES REQUIRED TO CONTINUE ADMINISTRATION OF PROGRAMS AT CURRENT SERVICES LEVEL IN FISCAL YEAR 1984

	Positions	Amount
Bureau of Health Care Delivery and Assistance:		
To restore management of categorical programs in 1984	[1]364	[1]$17,380,000
Existing 1984 President's budget	343	20,091 000
Total, 1984 program support (current services)	707	37,471,000
Bureau of Health Professions:		
To restore management of health professions programs	72	5,080,000
Existing 1984 President's budget including 14 new positions[2]	258	12,527,000
Total, 1984 program support (current services)	330	17,607,000
Bureau of Health Maintenance Organizations and Resources Development:		
To restore management of health planning programs	130	6,214,000
Existing 1984 President's budget	231	10,627,000
Total, 1984 program support (current services)	361	16,841,000
Program management:		
To restore overall agency management of programs	55	6,677,000
Existing 1984 President's budget	162	10,782,000
Total, 1984 program support (current services)	217	17,459,000

[1]Excludes 66 positions and $3,498,000 for the family planning activity which has been transferred to the Office of the Assistant Secretary for Health.
[2]The new positions are budgeted at a total of $210,000 for a portion of the year.

COMMUNITY HEALTH CENTERS PROGRAM

Senator WEICKER. Congress, in the past, has maintained a substantial community health services program. Obviously, with the recession there are those persons who have lost their jobs and, therefore, their health insurance, and those who can't get jobs and have never had health insurance. I raise the same point with you I raised with the Secretary yesterday, which is that they have a real problem on their hands. Probably 22 or 25 million Americans have no health insurance or no health care, at least in any sort of a formal sense.

I would like to know exactly your evaluation of how bad this problem is and insofar as the health centers are concerned how we are responding to the medical needs of the jobless.

Dr. GRAHAM. I think part of the issue that you and the Secretary got into yesterday is beyond the scope of our agency or my appropriate comment. I know that there are discussions within the administration, and I think potentially between the administration and the Congress about specific alternative plans, and legislation which might support the needs of individuals who presently find themselves without health benefits coverage as a result of the economic conditions of the country.

Specifically within the community health centers program, those centers, both with our encouragement and even without the necessity of our encouragement, are doing everything they can to provide the receipt of services and receipt of benefits that they have been structured to provide to a beneficiary population.

The change of the status of those programs from direct Federal operation to a block grant operation would not necessarily change the essential nature of Community Health Center activities.

SATELLITE CLINICS AND CONTRACTUAL SERVICES

Senator WEICKER. To what extent do you use satellite clinics and contractual services to provide health care in areas of high unemployment?

Dr. GRAHAM. I think that this is a very common pattern. I would like Dr. Martin to respond to some of the specifics of that question if he would.

Dr. MARTIN. Yes, sir. The use of contract providers and satellites are already utilized by existing centers, particularly in areas of high employment. With the $60 million jobs bill augmentation which has been provided to health centers, our estimate is that the preponderance of dollars would be expended through contracts with private providers and public institutions that are already involved with the health centers in caring for that specifically targeted, unemployed population.

So I would anticipate a significant amount of the $60 million would be expended off-site from the health centers, but specifically by providers taking care of the unemployed people without health benefit coverage.

HOME HEALTH AIDES

Senator WEICKER. You also provide additional dollars to hire home health aides to provide outreach services to the elderly and other homebound individuals. How have you implemented this effort?

Dr. GRAHAM. We are fairly far along with being prepared to implement it. I don't believe we have received any grant requests yet.

Dr. Martin?

Dr. MARTIN. In the case of the $5 million which was made available for hiring 550 home health aides, we have identified those targeted high unemployment areas. Community health centers are being notified this week to work out relationships with certified home health agencies, if they lack such certification themselves.

We anticipate obligating the money prior to the end of June through supplemental applications. We are not going to require community health centers to go through a new community health grant review.

With regard to the $5 million that was targeted for the section 339 program, the agency is preparing an implementation plan which will hopefully allow us to implement at least the grant part of that developmental program without final regulations.

We will try to use some type of interim regulatory approach, but that particular statutory design requires a competitive grant cycle so that everybody is allowed to come in to compete for the grant funds.

We still anticipate and hope that we can award the section 339 funds for developmental activities no later than the end of August. The loan components of that section are more complex because it is a much more complicated program to establish. But we will have obligated, we

hope, $5 million for new Home Health Agency activities by the end of August, and the $5 million for the 550 home health aides by the end of June.

MATERNAL AND CHILD HEALTH BLOCK GRANT

Senator WEICKER. Those people standing, feel free to sit at the end of the table.

In the recent jobs supplemental, Congress put a substantial additional amount of money into the maternal and child block grant—an amount, in fact, that went well above the authorized level for the program. Nevertheless, we all agreed that the extra money was needed to bring essential health care to mothers and children in areas of high unemployment who may be without such care.

The Congress was concerned that this money be put to use as quickly as possible. I would like to now get a report on exactly what has happened to it.

Dr. GRAHAM. Dr. Martin and his staff have already prepared the necessary communication to each of the Governors or responsible individuals in the Governors' offices. These were signed this week and sent to them.

All we require prior to the disbursement of funds is an assurance from a responsible individual in the State government that these funds will not be used to offset or supplement other non-Federal funds; that they will be used as new money.

We already have five telegrams in from States, giving us that assurance. We are very close to being able to obligate those funds as soon as all the proposal requirements are met.

Senator WEICKER. At the time we were considering the appropriation, we discovered that the States still had not drawn down some $69 million from their fiscal 1982 allotments for the maternal and child health block grant. How could this happen?

Dr. GRAHAM. Did I understand you to say fiscal 1982?

Senator WEICKER. Fiscal 1982; that's correct.

Dr. GRAHAM. Dr. Martin?

Dr. MARTIN. Senator, the mechanism under which a State health department draws down title V money is that the first dollars the States obligate are obligations incurred against State dollars. The State match is spent first. Then the second step occurs when the bills from providers within the State are submitted to the State and the State in turn draws down upon the Federal grant.

The State doesn't ask the Federal Government for the Federal share of the money until it is actually time to pay those bills. As an example let's pick an institution—such as the C&Y in Hartford—which is providing care in fiscal year 1983. The first dollars to pay for that care come from the State appropriations. Then, only when C&Y has actually submitted its bills to the State and the State has approved them, does the State begin to draw on the Federal grant.

The relationship of that $69 million and the services actually provided is mostly a technical fiscal issue.

The fact is, the 1982 appropriation provided service in 1982. It is just a question of delayed billing by the State, due to the processing of the bills, and insuring that there has been adequate collection from other third parties.

I think the concern of the committee is: Did we provide those services in 1982? And the answer is "yes" even though the billing process lagged sometimes 6 or 9 months beyond when the services were actually rendered.

INFANT MORTALITY RATE

Senator WEICKER. There has been much concern that with breadwinners losing their jobs and health insurance in the current high unemployment, families aren't getting the health care they need, and the infant mortality rate may be going up. Would you like to comment on that? Has it been going up?

What is it that has been going up if it has?

Dr. GRAHAM. I think there have been extensive discussions already between Dr. Brandt, whom you will be talking to later this morning and other elements of the Congress on this.

My understanding is that the trend line of infant mortality, according to the best available data, is still a downward trend; that the areas of concern that some have pointed out have been around preliminary statistics from individual States.

Again, my understanding of reading the discussion of this is that in the individual States, from time to time, there may be a variation in their own infant mortality statistics, but that variation has frequently blipped in a 1-year point and returns to the trend line in succeeding years.

The most important thing to us is that, based upon both final data available and preliminary data available, the trend line for infant mortality continues to decline.

Senator WEICKER. What is our infant mortality rate right now per 1,000?

Dr. MARTIN. The provisional rate for 1982, forecast on the last data, is 11.2 per 1,000 live births. The last information we have with respect to race would be from 1979. At that time, the rate for the total United States was 13.1, the rate for whites was 11.4 and the rate for all others was 19.8.

The decrease continues through 1982 according to the last data we have.

Senator WEICKER. As interest, counsel was wondering whether the overall rate is 11.4?

Dr. MARTIN. No; the overall rate for 1982, according to provisional data, is 11.2. I was giving you data relating to races.

Senator WEICKER. The rate for white is 11.4; for nonwhite is 19.8?

Dr. MARTIN. Those numbers are correct based on final data for 1979.

NONWHITE INFANT MORTALITY RATE

Senator WEICKER. Nonwhite, the mortality rate now stays at 19?

Dr. MARTIN. There was still a differential in 1979 between white and other races. In 1982, even with the decrease in the overall rate to 11.2, there continues to be a differential between the black population and the white population. The white population would be less than 11.2. The black infant mortality rate would be in excess of 11.2.

There still is a disparity between the infant mortalities.

Senator WEICKER. I am not interested in the disparity; it seems 19 is awfully high.

Dr. MARTIN. The 19.8 has been reduced somewhat so that rate is continuing to fall at the same rate. So that as the overall rate declines, both the white and nonwhite are decreasing at the same rate. But there is still a difference between the two.

Senator WEICKER. I would be interested to know as to what has happened, considering the hard times, on the nonwhite infant mortality rate. That probably was indicated as a problem. They are the ones that—let's face it—have less health insurance, less available for medical facilities, even under normal circumstances. So if the circumstances become abnormal, which I think most people would consider they are now, that could very well go in the opposite direction.

Dr. GRAHAM. There are individuals in the room that are far more expert on this than we are that you will be talking with later in the morning.

I would be happy to make sure we provide you with the most up-to-date information that is available to the Public Health Service on those questions.

Senator WEICKER. Who is here? Is there anybody with a comment to make on this point while we are at it?

Dr. GRAHAM. Mr. Chairman, Dr. Brandt is here.

Senator WEICKER. Why don't we just wrap this up while we are on it and not go back over it.

Statistically, where do we stand from your vantage point?

DECLINE IN INFANT MORTALITY RATE

Dr. BRANDT. At this time, the data from 1982 indicates the infant mortality rate overall is lowest in the history of the United States and is still falling. The trend line indicates about a 4-percent-per-year decrease.

The rate of fall is approximately the same for white and nonwhite groups, although the nonwhites have a higher rate.

The basic problem is that there is a much higher incidence of low birth-weight infants in the nonwhite than the white group. The intent is to decrease the number of low birth-weight infants as rapidly as possible. We have identified a number of risk factors that are associated with having a low birth-weight infant.

They include such things as smoking during pregnancy, and drinking during pregnancy, both of which have a dramatic influence on birth weight. They include a lack of adequate prenatal care, poor nutrition, and other factors associated therewith.

We have set ourselves a goal to reduce the overall infant mortality rate to 9 per 1,000 live births by the year 1990. I am convinced after having just reviewed our progress about 2 weeks ago, that we will achieve that goal significantly before 1990.

FLUCTUATION OF INFANT MORTALITY RATE

Senator WEICKER. Do you find there has been any fluctuation in what you describe here within the past, let's say, 12 months?

Dr. BRANDT. There is always fluctuation every year. For the past 10 years, somewhere between 10 to 15 States every year show an increase in infant mortality compared to the year before.

Part of this is just a statistical problem. If you take a small State like Rhode Island, for example, one or two additional deaths or one or two fewer deaths in any one year causes a dramatic shift. Rhode Island has a birth rate of about 13,000 births per year.

If you take large States like California, Texas, Michigan, and so forth, you get a much more stable outlook. But we see fluctuations every year as the rates come down.

Senator WEICKER. But the fluctuation I refer to is relating to the overall problem which everybody, including the Secretary, those here today, and Congress, concedes is a problem arising from the difficult economic times of the past 12 months and the failure of the substantial element of the population. Twenty-two to 25 million people do not have health insurance or access to programs of medical care.

That's why I was asking whether under those circumstances this is something that can be tracked at this juncture, or are we going to have to wait before we get those statistics?

Dr. BRANDT. It can be tracked.

Let me explain two things. First, we receive provisional estimates. These estimates are based on births that occur in a given State. Then, we get final data which are based on the births of residents of a State.

For example, nearly 15 percent, as I recall the figure, of the births in the District are from residents in other States, particularly Maryland. We get a provisional rate for Washington or the District that has to be adjusted to remove the people who are actually residents of another State.

At the present time, using provisional data on births, not necessarily to residents, but rather by place of occurence, we do not see any change from the downward trend that has been going on since the late sixties.

EXCEPTIONAL FINANCIAL NEED STUDENTS

Senator WEICKER. Thank you.

In fiscal 1984, you propose to completely eliminate funding for National Health Service scholarships. If you are successful, funding for the program will have gone from $43 million in fiscal 1982 to $11 million this year to zero next year.

In the meantime, you continue to fund in fiscal year 1983 the exceptional financial need scholarship program which assists low-income medical students through their first year of training.

How will the exceptional financial need students pay for their second and future years of training if they cannot get assistance from the National Health Service Corps scholarship program? Do you expect them to resort to the very expensive health guaranteed student loans?

Dr. GRAHAM. We anticipate there are at least two sources of potential financial support for the EFN students.

One would be the health professions student loan fund, which is still maintained and obligated by the individual universities. That is a rotating loan fund with an interest rate of about 9 percent at the present time.

The HEAL loan fund, because it is tied to the Treasury bill, has a fluctuation in its interest rate. It is not as expensive now as it was 1 or 2 years ago. As a matter of fact, it is approaching the health professions student loan fund rate.

Those would be the two loan funds that have some degree of Federal involvement in them and would be available to such students.

There also would be sources of private support in terms of commercial money.

Senator WEICKER. Do you think this is going to be adequate?

Dr. GRAHAM. I think a student who is entering a second or later year of a professional school has, at that point, a more than reasonable expectation of graduation and employment in that field; and with the loan fund availability and the present interest rate on those loans, it is not an unreasonable risk for financing the education.

NATIONAL HEALTH SERVICE CORPS

Senator WEICKER. I have some concerns here in the sense that we are still going to have large segments of our population underserved—the rural poor, inner-city. You don't have any concern they are being adequately served there? That is a big concern to me.

I don't worry about the general doctor population; they are going to do well. But it seems to me that there are some pretty tough situations out there that are drastically underserved at the present time.

Dr. GRAHAM. I share your concern, but it is an area where I think that we have made substantial progress, and we have every reason to believe that additional progress will be made in the coming years, even setting aside what may be going on because of the increasing physician supply. The fact is that some physicians are practicing in areas where perhaps there were none before.

The National Health Service Corps' field strength, both those who would be employed as Federal providers and those who would elect to

provide service under the private practice option, over the next 5 or 6 years, is going to stay very high.

We are in a position to place more people in underserved areas than we ever have been before. We are also starting to find, with the aggregate increase of physician population in urban areas, that the individual community health centers, where we have been placing a fairly substantial number of physicians in recent years, are now telling us they are having increasing success in being able to hire physicians. And that is causing us to look at our placement policies and placement priorities in terms of putting obligors, individuals who have 3 or 4 years of obligated service before them, in the more hard-to-access and hard-to-get-to areas.

So I think, although to some extent it is conjectural as to where we will be in 1987 or 1989 because of other factors, that we are on a track where over the last 10 years, we have seen substantial improvement in the physician-to-population ratio in rural and in inner-city areas of the United States. And there is every reason to believe that this practice will be maintained.

NATIONAL HEALTH SERVICE CORPS STAFFING REQUIREMENTS

Senator WEICKER. On page 80 of your justification, you make the following statement: "At the present time, the scholarship recipients who are now in the pipeline and subsequently obligated to serve will provide a sufficient base of health personnel to meet the essential short-range staffing requirements of the corps. Options regarding future needs for the recruitment, placement, and retention of National Health Service Corps personnel is being studied."

Well, what you are saying to me is we are fine for the immediate future here, but that doesn't answer what the problem is in the long range.

What options are you considering and when will the study be completed?

Dr. GRAHAM. We are preparing within the Department and for submission to the Congress, reauthorization of the National Health Service Corps legislation and the health professions student assistance legislation, both of which expire at the end of fiscal year 1984.

We feel there are some things that we can look at and potentially propose to the Congress that will allow us, even in the years past 1990, to address these issues and in a more flexible manner than the current scholarship program which now has a 7- to 9-year lead time on what it allows us to do.

FUNDING FOR NATIONAL HEALTH SERVICES CORPS

Senator WEICKER. I suppose what puts it in stark contrast to me is when I see programs such as the National Health Service Corps scholars, going from $43 million to $11 million to zero. And this touches in some ways on the philosophical differences, I suppose, between myself and the administration.

I just returned from Cuba, and I will tell you, they are increasing funding, insofar as the health services are concerned, for medical schools, and nursing schools.

I think you know as well as I do what the needs are in that part of the world. Those people are arming themselves, not in the traditional concept—that's not my department; I am sure they are doing that also—but they are arming themselves not to serve their own people, but serve that part of the world.

I see us going like this [indicating down] just internally. And I tell you where I think the strength of this Nation is. It is in these types of funds being expended and to give us great depth in terms of our doctors and scientists and nurses.

I get very nervous when I see this type of a trend line because I know that you are going to achieve something that might be of budgetary significance this year, but certainly you better than anybody else at this table know you don't train a doctor over night. And there is a price to be paid in the out-years.

We could suddenly wake up in the morning, 5 or 6 years hence, and say, "My God, we don't have enough doctors." You are really setting the future course by what we are doing right now. I'm not so sure I want to do it this way.

Dr. GRAHAM. No; I don't want to try to anticipate too much what the outcome of our legislative considerations would be within the Department or the administration. The philosophic concern that you express, though, is not inconsistent with the types of issues and types of concerns we have been discussing within the Public Health Service.

The National Health Service Corps, and the particular mechanism by which we have generated obligated service, has played a major role in the last 10 years, I think, in addressing some very real needs.

It is also, as we have come to recognize, a potentially and, in some cases, specifically cumbersome, inflexible tool. What we are looking for is a way where individuals might be available for public service, whether you would call it obligated service or voluntary service, but in a manner that is much more flexible and which allows individual Secretaries and individual Congresses within the range of their own policy priorities and budget priorities to decide whether they feel that they can afford 50 or 5,000 physicians in a given year.

I think, as you are well aware, one of the difficulties in the scholarship program is that we, by design, have to aim 7 to 9 years ahead. And that means we have to give an entering medical student a scholarship the first day he or she comes into medical school and says: "I really want to be a family physician;" and 7 years later, really wants to be something else.

That was the best we could do when we started the program in 1970. I would never argue we shouldn't have done it then. But I think we have learned in the succeeding years we can consider some alternative ways to have that same capacity because it does become a matter of national policy and resources are there to expand our medical presence in either underserved areas or international areas.

I would hope we have the wisdom to construct a program that the Congress can consider and decide whether or not that meets the needs.

NATIONAL HEALTH SERVICE CORPS SCHOLARSHIP DEFAULTS

Senator WEICKER. I understand you have 1,565 persons whose medical education largely or wholly was paid for by the Federal Government and who have an obligation to serve in the National Health Service Corps, and currently are in breach of their contract. And the potential bill for these breaches of contract, according to your agency, is $36 million.

The 1,565 were from among 13,000 students who received Health Service Corps scholarships in the last 10 years. And the Government paid out roughly $441 million for those scholarships during that period of time.

I understand that most of these 1,565 are doctors.

Dr. GRAHAM. Yes.

Senator WEICKER. So now, what do we do to get our money back?

Dr. GRAHAM. Well, the first thing we try to do in dealing with the individuals who may have gone into default is to try to convince them that it wasn't a very good idea, and it is going to be a lot easier for them and a lot more helpful to the country if they go ahead and provide the obligated service in the manner that they contracted for.

We are working with them to try to identify what the problem is, and to try to encourage them to rethink that provision.

I think, as you are aware in the law, for many of the people going into default right now, the penalty is a three-times penalty. It is not just paying back with interest what we paid on their behalf. It is three times that with interest, which is a substantial amount of money for any individual, whether a physician or not.

If we have, though, after a decent period of working with them and discussing what the options are and what the problems are, individuals who are totally recalcitrant, we move to appropriate legal actions to recover those funds.

Senator WEICKER. Do you have a specific program within the agency right now?

Dr. GRAHAM. If you would like to pursue that, I would like to have Dr. Martin discuss that in a little more detail.

Senator WEICKER. You are absolutely right. If I got that money back, I would have more than enough funding to take care of what I am asking for.

Dr. MARTIN. I think, first of all, Senator, the 1,553, which are data as of December 31, 1982, needs to be dissected a little bit. That includes 311 people who flunked out of school, did not complete their education.

Senator WEICKER. So we are talking about 1,200.

Dr. MARTIN. Now, we are down to 1,242. Of the 1,242, about 85 percent of them are what we call the "old law" individuals that took the scholarship money under the previous scholarship program in the mid-seventies that had no triple payback penalty.

Basically, what that ended up being was a student loan, because all they had to do was pay the principal plus interest. If one was not interested in going to an underserved area, it was far more economical to simply pay back the interest on that particular loan rather than provide service.

Most of those individuals, given the character of the amount of money they owe, are beginning to pay back. So that some $37 million is the gross figure for the aggregate of all the dollars owed.

A significant proportion of scholarship awardees in that first repayment category that did complete school and had the old scholarship, are beginning to pay back on a phased payback plan. In the last year, there have been a significant number on the new program, which is the triple penalty—now, we are only talking about 177 practitioners. Those individuals owe an average of $57,910.

We have carried out a fairly aggressive effort to collect that money. We contact them; we refer them to collection agencies; and, in a number of fairly important cases, we have referred them to the Justice Department for prosecution.

So I would have to say, if you were one of those payback individuals out there, you would not think at this point in time that we are not being aggressive in pursuing receipt of that money. And we intend to pursue, if necessary, through litigation or prosecution those individuals that clearly the Federal Government has claim against.

So the 1,553, I think, is an overstatement of the number of truly delinquent people, given the expectation of their being able to repay. On the other hand, the $30 some million is clearly what is owed to the Government. I am fairly optimistic that over a reasonable period of time we will collect the bulk of that money, because we are certainly going to be very aggressive about getting it.

We would prefer that they serve.

PRIMARY CARE PROGRAMS

Senator WEICKER. I am surprised to learn that you proposed to cut $11 million from your support of primary care programs, including support for developing family medicine departments at medical schools.

At a time when we seem to be making headway toward getting family physicians into underserved areas. why would you reduce this important source of funding for the training of such doctors?

Dr. GRAHAM. I think we should go back a little to where we started our conversation about what is the fiscal year 1983 baseline. I want to leave no question in your mind; we regard family medicine as a very important priority, and we are quite supportive of this program.

The amount of support for that activity in the President's 1984 budget is consistent with the budget line that the administration has submitted to the Congress for the last 3 fiscal years.

The apparent reduction is because there was an action on the part of the Congress last year which substantially increased the family medicine line in the 1983. continuing resolution. We regard family medicine as

important within the relative priorities that we feel we can fund. Within the health professions area, it has a very high priority.

That apparent reduction is simply a consistent submission for support on the part of the administration.

Senator WEICKER. Consistent—in other words, consistent with their request, but not with the Congress?

Dr. GRAHAM. Yes; that's correct.

Senator WEICKER. Well, I suppose what we are saying is that the administration consistently makes these requests that are inadequate to achieve the proclaimed desired result. And the way I read this off of the line for family medicine and general dentistry residency and training, $34 million, fiscal year 1983; fiscal year 1984, $23,738,000, reduction of $10,262,000.

General internal medicine and pediatrics, $11,412,000, $12,040,000, up $628,000.

And family medicine departments. from $8,840,000, down to $7,436,-000, a reduction of $1,404,000, with an overall total reduction of $11 million.

Dr. GRAHAM. I understand the base of the congressional action because we are requesting what was made available last year.

Senator WEICKER. Senator Burdick.

Senator BURDICK. I am sorry I am late.

I was looking at the record very carefully, and I have no questions at this point.

NURSE TRAINING PROGRAMS

Senator WEICKER. Nurse training.

Staff, in propounding these questions, keeps on using the statement "I was surprised, we were surprised." I am not surprised at what is going on around here, so don't use that phrase.

The budget proposes to cut the nurse training programs by some $35 million in fiscal 1984, compared to fiscal 1983—from $48.5 million to $13.2 million. And while we have more than 1 million nurses employed in the United States today, you have only to pick up the want ads to see how much in demand nurses are.

I have to ask why you propose to make a 73-percent cut in nurse training.

Dr. GRAHAM. Historically——

Senator WEICKER. I might just finish on this point.

The Institute of Medicine in its recent report on nursing recommends that the Federal Government maintain its general programs of financial aid to postsecondary nursing students to assure maintenance of what IOM believes will be a sufficient supply of nurses.

All right, go right ahead.

Dr. GRAHAM. Historically, I believe it has been the view on the part of the Federal Government that participation in the health professions area has been largely oriented to assuring that there is an adequate supply of specific types of health professionals, some concern about distribution, some concern about access.

As early as 6 or 7 years ago, there came to be a feeling on the part of many in the Federal Government that the supply of nurses was adequate, that there was not a shortage of nurses, and that the continuation of large amounts of Federal support for nurse training would not necessarily address what the problems might be in the nursing community as they related to a shortage or adequacy of supply.

Our request this year again is consistent with previous requests by both this administration and prior administrations for level support in nurse training. It is less than the Congress provided in the 1983 continuing resolution, hence the percentage reduction as you quoted.

We are aware of the Institute of Medicine report which was not available to us prior to the time that this budget was developed. The IOM has advocated a continuation of a certain level of Federal support in this area and has specified a number; but I believe even the institute caveated that number by saying that it was an estimate, without being placed in the context of what other competing demands might be.

In other words, it was an estimate on the part of a study group and what they thought might be helpful to carry out some of their recommendations, but was not a budget estimate.

Senator WEICKER. Well, first of all—and this is just a layman's point of view; but it seems to me you have a great disparity here in whether there is a sufficiency of nurses.

There are two situations, I think, that are going on here.

No. 1, the suburbs are very nice places to practice in. And I am sure that salaries paid by these private hospitals are fairly substantial.

Inner-city hospitals, that is a different story entirely both as to the environment and as to the pay.

Believe me, I think there is a terrible shortage there and also in the rural poor areas. It would seem to me that this is hardly a call for a reduction in nurse training.

I suppose the other thing—and you know more about this than I do as a physician—is that more and more, your overall profession is increasingly delegating duties to those that are not physicians. So I can only imagine the nurse's position in all this to continues to be elevated.

All of that doesn't jibe with the 73-percent cut.

Dr. GRAHAM. Even the Institute of Medicine study, though, did find that in the aggregate, there was no shortage of nurses. They made a series of recommendations about better utilization, and their concerns about work—the environment and pay.

Most of those issues are beyond appropriate Federal purview when you start talking about individual working conditions, what the pay scales are for nurses, and the other issues that the group studied.

CENTER FOR NURSING RESEARCH

Senator WEICKER. The Institute of Medicine, however, also called for establishing a "Center for Nursing Research" as they need a focal point for promoting the growth and quality of nursing research.

Have you thought about that concept in seeking legislation to implement it?

Dr. GRAHAM. As part of the review for the expiring health professions activities, we are examining the Institute of Medicine report very closely and taking its recommendations into consideration as we prepare our legislative drafts and discussions within the Department.

Whether or not, in the final outcome, we will propose the establishment of such a center or augmentation of the present nursing research activities would be premature for me to speculate, but it is being considered.

PREVENTIVE MEDICINE RESIDENCIES

Senator WEICKER. You propose to spend $1,055,000 on preventive medicine residencies next year for 30 residents. Your budget narrative indicates a shortage of 1,750 preventive medicine physicians by 1990. At that rate, it would take 58 years to meet the shortage through this program.

So the question, naturally, arises as to why we should devote any money to an effort that seems largely symbolic and will have little practical effect on the problem.

Dr. GRAHAM. Our feeling is that there is again an important Federal role to be played in taking an initiative and providing some examples, some seed money, for the beginning of what we would hope to be a program that would come to be supported not just by the Federal sector, but by State and by private enterprise.

If I may use the example of family medicine, which I know more about, there has been a very reasonable Federal investment in family medicine over the last 10 years. And yet, if you look at the total amounts expended for support of family medicine residencies over the last 10 years, the Federal share is probably less than 30 percent.

Part of what we hope is that in the preventive medicine residency area, we can provide support to get some of these programs organized, to increase the visibility that they may have now, to bring it to mind to more and more graduates of medical school that this is a potential professional endeavor, and that additional State support, additional institutional support, might be forthcoming to augment our efforts rather than just assuming that there will be nothing there than the Federal effort.

HEALTH PLANNING PROGRAM

Senator WEICKER. Would you give the committee your attitude toward the health planning program?

Dr. GRAHAM. I think it is very clear that our position of record is that the Federal role in health planning should be phased out.

Senator WEICKER. But that, of course, is not the congressional intent.

Don't you think we ought to wait until Congress acts, presuming they act?

Dr. GRAHAM. Well, it is our responsibility to propose a budget to you which is consistent with the administrative philosophy that we have. But congressional action——

Senator WEICKER. But I trust you are not shutting this down in anticipation.

Dr. GRAHAM. No, sir. We are carrying out the law.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. I have no further questions although I will have questions for response to the record.

Senator Burdick, do you have any further questions?

Senator BURDICK. I will pass.

Senator WEICKER. Thank you, gentlemen, for your appearance here and your responsiveness to all the questions.

And as I said, I would appreciate it if the staffs got together and ironed out any difficulties of translation.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

Questions Submitted by the Subcommittee

SUPPLEMENTAL PAY RAISE COSTS

Question: Can you tell us why you are projecting a 1983 pay raise cost increase of $8,504,000 for the Health Resources and Services Administration, exclusive of Indian Health activities, while the Center for Disease Control, with slightly more personnel, will be able to get along with an increase of only $6,019,000 -- about $2.5 million less? Even recognizing the fact that staffing in one program is going down while staffing in the other program goes up, the discrepancy seems to be unduly large. Health Resources would get about 30 percent more money than CDC.

Answer: These pay raise costs are based on the number of positions the agency is funding in 1983. In 1983 the Centers for Disease Control (CDC) supports 616 "in lieu of cash" positions from grant funds to states from the Veneral Disease Control, Immunization and Preventive Health and Health Services block grants. These must be deducted from the 3,698 total positions shown in the budget in order to compare them with the Health Resources and Services Administration (HRSA) position levels. Making this adjustment and further adjustments for comparable transfers, a more accurate comparison can then be made.

In 1983 HRSA is requesting pay raise costs of $8.5 million for 4,143 positions. The CDC is requesting $6.0 million for 3,082 positions. Average pay raise cost per position is almost identical for both agencies.

PAY RAISE

Question: You plan to transfer $2,842,000 from unobligated PHS hospital construction funds to cover a portion of the costs of the 1983 pay raise. How much in total would remain in the PHS hospital construction account after this transfer?

Answer: If this plan is approved, $8,093,000 would remain in he PHS hospital construction account. This amount has been committed to projects previously approved by Congress in fiscal years 1982 and 1983 totaling $7,993,000 for the National Hansen's Disease Center and $100,000 to the Seattle Hospital as part of the PHS final obligations related to the transfer of the facility.

FEDERALLY SUPPORTED FACILITIES

Question: Dr. Graham, on page 6 of your prepared testimony you state that your resource development budget will be used in part to "ensure that those facilities that previously received Federal funding comply with requirements to provide a reasonable level of uncompensated care to persons unable to pay". What constitutes a reasonable level of uncompensated care?

Answer: The uncompensated services regulations define "reasonable volume of services" to persons unable to pay as the lesser of 10 perc nt of the Federal construction assistance received (adjusted annually by an inflation factor) or 3 percent of the facility's operating cost. Facilities are required to provide this volume of services annually for a period of twenty years from the

time construction was completed. The period may be shortened by providing verifiable excess services, or extended if deficits are incurred.

RETENTION PAY BONUSES

Question: Dr. Graham, the administration is proposing the extension into 1984 of language, first inserted in the continuing resolution, prohibiting the payment of special retention bonuses to National Health Service Corps physicians who have to serve because they received scholarships.

Some professionals have said that this provision has had an adverse effect on the staffing of rural community health centers because physicians can and are satisfying their service requirements by leaving the Corps and entering into "private practice" arrangements in urban health manpower shortage areas. These doctors are said to be the same Corps physicians that would normally serve remote rural areas that have trouble attracting doctors.

What's your response to this change?

Answer: The major purpose of the Commissioned Corps and Civil Service salary bonuses is to retain physicians in government service. It is inappropriate to provide retention pay bonuses to physicians who are obligated to serve. Therefore, the Administration requested that bonus pay to these physicians be eliminated.

During FY 1982, the Private Practice Option (PPO) grew rapidly, but maintained a distribution that was 60 percent rural and 40 percent urban. As of March 18, 1983, 46 percent of the matches this fiscal year have been to urban areas and 54 percent have been to rural areas. We intend to maintain our support for poorly served rural areas by giving these sites, which cannot attract providers on the open market or participate in the national diffusion of health manpower, the highest priority in 1984 for the placement of Federal assignees. Concurrently, we are restricting the placement of both Federal and PPO assignees to areas with the greatest need. This should assure that the needs of remote rural sites are not neglected, but rather receive the attention that was intended in the NHSC legislation.

Question: On page 81 of your justifications you indicate that you propose not only to continue the existing prohibition against the payment of special retention bonuses to physicians obligated to serve in the National Health Service Corps because they received scholarship assistance but also to reduce the salaries of new obligated physicians by $9,000 per year by the elimination of physician comparability pay.

Won't this accelerate the flow of these physicians into the private practice option and thus further damage remote rural areas?

Answer: The major purpose of the Commissioned Corps and Civil Service salary bonuses is to retain physicians in government service. It is inappropriate to provide retention pay bonuses to physicians who are obligated to serve. Therefore, the Administration requested that bonus pay to these physicians be eliminated.

It is anticipated that a greater percentage of the scholarship physicians completing training will elect to service their obligations through the PPO instead of Federal employment in either personnel system; and, in accordance with the legislative proposal, the Secretary may grant all PHS officers, including Federally salaried assignees who have completed their obligation and who serve beyond the period of obligation, additional special pay.

Areas which cannot attract providers on the open market or participate in the national diffusion of health manpower, remain the highest priority in 1984 for the placement of Federal and PPO assignees to areas with the greatest need. This should assure that the needs of remote rural sites are not neglected, but rather receive the attention that was intended in the NHSC legislation.

FUTURE PLANS

Question: Your decision to terminate National Health Service Corps scholarship assistance will obviously have an adverse effect on Corps staffing. You state on page 80 of your justifications that "options regarding future needs for the recruitment, placement and retention of National Health Service Corps personnel are being studied".

What options are you considering and when will the study be completed?

Answer. Options for the future needs for health professionals are based on the long-term availability of such personnel in the United States. The time frame currently being examined is the 10 year period from 1984-1994. A number of private and Federal research studies indicate that the distribution of health manpower during this period will continue to expand, increasingly thrusting both primary care providers and specialists into areas previously unserved or underserved. The future requirements for the Public Health Service (PHS) will be based on the identification of areas which for economic or other reasons will probably be unable to attract an adequate supply of health manpower. To meet these needs and to promote the rate of diffusion of health manpower, the PHS is considering a limited renewal of the scholarship program, a program of loan forgiveness in exchange for an agreement to serve in an underserved area for a fixed period, and the use of volunteers who, as Federal employees, would work in underserved areas.

Preliminary recommendations of the study group have been completed and are currently being reviewed within the Department.

Question: When will the recommendations arising out of the study be made available to the Congress?

Answer: The recommendations are currently being reviewed within the Department and are expected to be ready for initial presentation to the Congress with submission of the Department's legislative plan for FY 1985.

CONSULTANTS

Question: On March 14th the Department submitted a report on consultant services which indicated that the Health Resources and Services Administration spent only $3,766,000 on consultants last

year but plans to spend $7,112,000 in the current year and $6,338,000 in 1984. Why have these costs gone up so rapidly in an overall budget that you plan to cut by over 50 percent between 1982 and 1984?

Answer: The consultant services costs did not increase as rapidly from 1982 to 1984 as it appears. The increase occurred because fiscal 1982 Bureau of Health Professions plans did not materialize and had to be carried out in the subsequent fiscal year. Although the Bureau's programs have been reduced over the past several years, the Health Professions Analytical Studies and Report program - which comprises the bulk of the Bureau's consultant services costs - has been funded at the same level over these years with a minor increase in fiscal year 1984.

DEBT COLLECTION

Question: Dr. Graham, on page 6 of your prepared statement you talk about efforts to reduce the loan delinquency rate at health professions and nurse training institutions. What is the current delinquency rate and what is your target rate for fiscal year 1984?

Answer: As of June 30, 1982 the average 90-day delinquency rates of borrowers and loan dollars are as follows:

	Percent of Borrowers	Percent of Loan Dollars
TOTAL Average Rate	15.64	11.09
MODVOPP Average Rate	8.68	8.51
Allopathic Medicine	8.11	8.52
Osteopathic Medicine	7.99	6.51
Dentistry	8.09	7.85
Optometry	10.36	9.63
Pharmacy	10.49	10.08
Podiatric Medicine	20.76	19.89
Veterinary Medicine	4.34	4.44
Nursing Average Rate	21.07	15.73
Assoc. Degt. Nursing	29.85	23.99
Diploma Nursing	17.00	1.88
Baccalaureate	6.83	13.09
Graduate Degree	9.96	8.60

According to the final Health Profession Student Loan and the Nursing Student Loan proposed regulations to be submitted for publication in the Federal Register the week of April 11, 1983, we will measure dollar delinquency rates based only on loans that are in arrears for more than 60 days. Our target is to reduce delinquency to no more than 5% over the next two years.

HEALTH PROFESSIONS LOAN DELINQUENCIES

Question: According to "The Blue Sheet", a proposed rule currently being reviewed by the Office of Management and Budget would require that a school be dropped from the Health Professions Student Loan Program is 5 percent of both loan dollars and borrowers are delinquent. OMB wants to tighten this standard by basing disqualification solely on the dollar amount. Why wouldn't this be a wise thing to do?

Answer: We understand with OMB's contention that delinquency might be most appropriately calculated only on dollars. We are discussing the submission of the HPSL final rule and a New Proposed rule for concurrent publication in the Federal Register, indicating that delinquency will be calculated on dollars only.

Question: How many schools currently benefitting from the student loan program would be disqualified under the 5 percent standard if it were applied to both loan dollars and borrowers and how does this compare to the number that would be disqualified if only the dollar standard were used?

Answer: Using a current 90-day dollar and borrower delinquency data and a 5 percent performance standard HPSL schools would be affected as follows:

	No. of Schools
HPSL universe	310 schools
Schools not reporting	10
No. of reporting schools	(300)
. borrowers and dollars above 5%	157
. dollars only above 5%	162

Question: You state on page 56 of your justifications that final debt collection regulations for the Health Professions Student Loan program are expected to be published in the Federal Register during March 1983. Have the final regulations been published and, if not, when will they appear?

Answer: The final Health Professions Student Loan regulations will be submitted for publication in the Federal Register soon. Currently they are in final review status by the Office of Management and Budget.

Question: On page 88 of your justifications you state that "emphasis will be placed on debt collection activities" related to National Health Service Corps operations. I wonder if you could be more specific. What is the total outstanding debt in this area, how much of this debt did you manage to collect last year, what are your debt collection targets for fiscal years 1983 and 1984, and how many debt collection staff will be on board in 1983 and 1984 as compared to the 1982 level?

Answer: The total outstanding debt at the end of fiscal year 1982 was $64,452,000, of which $28,677,000 was related to the NHSC field operations and $35,775,000 was related to the NHSC scholarship program.

In the NHSC field program, $16,125,000 represented current accounts in payment status. Only $12,552,000 were delinquent accounts of which $9.95 million is currently being processed for waiver consideration. The total debt collected in FY 1982 was $11,590,000.

In the NHSC Scholarship program, $25,778,000 represented non-current accounts. $3,067,000 represented current accounts in payment status with $6,930,000 in delinquent accounts. The total debt collected in FY 1982 was $3,984,000.

Our target for collection in 1983 is $9,000,000 for NHSC field and $5,690,000 for NHSC scholarships for a combined total targeted collection of $14,690,000.

For 1984, our target for collection is $9,000,000 for NHSC field and $5,059,000 for NHSC scholarships for a combined total targeted collection of $14,059,000.

The number of staff on board dealing with debt collection in 1982, 1983, and anticipated for 1984 is 63 person-years.

MANAGEMENT CONTRACTS

Question: You indicate on page 80 of your justifications that you are expanding your program of contracting for National Health Service Corps management functions formerly performed by Federal staff. The average cost of a contract increased from $120,000 in 1982 to a projected $140,000 in 1983. Can you tell us why?

Answer. During the first year of the contract, a considerable period is required for start-up activities such as planning, needs analysis, staff recruitment and internal organization. Costs are expected to be slightly lower during this period owing to hiring lags and a reduced level of project support involving travel. During the second year, when all staff has been hired and a higher level of support activity is underway, costs are estimated to be approximately 10 percent higher, and the increased average cost recognizes this circumstance.

Question: Why aren't you projecting an increase in costs per contract in 1984?

Answer. No increase in contract costs have been projected for FY 1984 because the budget requested will permit us to maintain adequate levels of support without increases in expenditures.

Question: How much on the average did it cost to perform the management functions now being contracted for when they are carried out by Federal personnel?

Answer: The basis for the State contracts program is to enlist the assistance of the States in carrying out functions that support meeting local health care needs. These functions include the assessment of needs and the development of plans to meet those requirements, the development of sites, the placement of NHSC personnel, and the monitoring of existing and newly established sites. The need for contracts is demonstrated in part by the increase in overall PPO and Federal field strength from 2,782 in FY 1982 to 3,283 in FY 1984. Similiarly, the number of scholarship placements will increase from approximately 900 in FY 1982 to over 1,550 in FY 1984. The State contracts do not represent a displacement of Federal personnel but rather a substantial supplement to our capabilities to identify and serve the needs of the medically underserved through the placement of NHSC health professionals.

FEDERAL EMPLOYEE OCCUPATIONAL HEALTH

Question: In looking at your justification for a $1,194,000 Federal Employee Occupational Health program in fiscal year 1984, I note that you project an increase in consultations from 100 last year

to 126 in 1983 and a continuation of the same level of consultations in 1984.

Since consultations involve the evaluation and establishment of Federal employee health activities and since 167 units will be in operation by the end of 1983 why shouldn't there be a decrease in demand for these consultations? When will you reach the saturation point?

Answer: In accordance with the authority contained in Public Law 658, 79th Congress, codified as 5 U.S.C. 7901, any head of a Federal department or agency who wishes to establish a health service program for its employees must consult with the Public Health Service. In addition, the Secretary of HHS, upon agency request, shall review health programs conducted under this section and in both instances submit comments and recommendations.

The requests for consultations are not linked solely to the establishment of DEFOH operated health units, but are generated by other existing agency operated health programs, and as long as agencies continue to need new health units or to operate their own units, there will be a demand for consultations and evaluation of these programs. We are unable to predict a saturation point for consultations since we cannot determine the total Federal government need in this area.

PAYMENT TO HAWAII - HANSEN'S DISEASE

Question: In estimating the costs of treating Hansen's Disease patients in Hawaii you are projecting a decrease in the cost of each outpatient from $74.61 in 1983 to $66.86 in 1984 yet between 1982 and 1983 you show a $2.19 per visit increase. Why do you think medical costs will decline in this area?

Answer. The number of outpatient visits in 1982 and estimated in 1983 was 1,600 patients. There was an inflationary increase of $2.19 per visit. The estimated number of outpatient visits in 1984 is 2,000. An increase of 400 outpatient visits per year with no significant increase in staffing will result in a lower cost per visit. For example, the cost of the outpatient program in 1983 is estimated at 1,600 visits x $74.71 or $119,376. In 1984, the outpatient costs are 2,000 visits x $66.86 or $133,720.

LOAN CANCELLATIONS

Question: Although you are proposing the elimination of all new funding for the Health Professions Student Loans program in 1984, the amount available for loans under the revolving fund will increase by almost 50 percent and there will be a comparable increase in students assisted. Can we expect comparable increases in future years and as a matter of sound policy is it wise to increase the number of direct loans this rapidly?

Answer: We anticipate that the amount of funds available in the HPSL revolving fund in 1983 will be $38.0 million - a revised estimate from the $29.0 million shown in the budget. That amount will increase by $4.8 million, to $42.8 million in 1984. It is projected that collections will approximate $41,000,000 for several years after 1984. Thus, moderate increases are projected.

HEALTH PROFESSIONS LOAN CANCELLATIONS

Question: You plan to end the appropriation of funds to pay schools for their share of Health Professions Student loans which are subsequently cancelled for service in shortage areas. Instead you would allow the schools to retrieve these dollars "when the revolving fund is returned to the Federal government". When will this happen and what will the schools do in the meantime?

Answer: Section 741(i) and 836(c) of the Public Health Service Act states that...

> "Where all or any part of a loan, or interest is canceled under this section, the Secretary shall pay to the school an amount equal to the School's proportionate share of the canceled portion, as determined by the Secretary."

The Department plans on paying schools their share of loans cancelled in 1987 when the loan fund is currently scheduled to be dissolved. It is assumed schools will use other operating funds until such time as reimbursement occurs.

FINANCIAL DISTRESS

Question: You are requesting $5.6 million to aid four health professions schools in acute financial distress. Can you tell us for the record what proportion of the students in each school are foreign nationals?

Answer: The percentage of foreign nationals are as follows:

Meharry Medical College	5%
Tuskegee Institute School of Veterinary Medicine	16%
Xavier University School of Pharmacy	7%

Question: Have you explored with these schools the policy of charging foreign students a tuition differential as a means of reducing the need for direct Federal support under the financial distress program?

Answer: The charging of a tuition differential has been explored with the Meharry Medical school. The school believes they receive benefits from the foreign countries who send students, which far out weigh charging a tuition differential to all foreign students. For instance, Malawi, in Africa, sends the largest proportion of foreign dollar endowment fund. A tuition differential could actually curtail gift giving from foreign countries. Meharry has also developed relationships with many African countries which involve international health activities, collaborative research efforts and faculty exchanges. These activities benefit Meharry more than a tuition differential.

Tuskegee does charge a differential of $9,600 to $11,500. The school contracts with many countries to take students. Of the 38 foreign nationals now enrolled, 23 are under contract and the newer contracts are at the $11,500 figure. The School finds that they benefit by not charging the differential to all foreign national students. Benefits include the development of international health efforts, collaborative research efforts and consultation contracts

which provide direct dollars support to the school more than off setting the dollars obtained through a tuition differential.

The charging of a tuition differential has been explored with the Xavier School. School officials believe a differential might be discriminating. Further the number of candidates applying to schools of pharmacy has been decreasing. A large tuition differential might drive qualified foreign nationals to other schools of pharmacy. A differential would also diminish collaborative efforts.

GRADUATE PROGRAM IN HEALTH ADMINISTRATION

Question: We realize that you plan to close out your Public Health Capitation grant and graduate program in health administration activities in fiscal year 1984. But can you tell us why under the program as currently funded the average contribution per public health student is $557 while the average contribution per health administration student is $748, over one-third more?

Answer: Although both the Public Health Capitation and the Graduate Program in Health Administration programs are institutional support activities, the distribution of funds is based on conditions which are not identical in both programs.

PRIMARY CARE

Question: Do you plan to continue the same differential between public health students and health administration students in funding your proposed special project grants?

Answer: The Public Health/Health Administration Special Projects program - proposed new legislation - would be a competitive peer-reviewed grant program. The grants will be reviewed and approved based upon the quality of the proposed projects. Awards would be based on the amount requested for a proposed project and not upon the number of students enrolled in a particular school or program.

Question: As you indicate on page 109 of your justifications, the general dentistry residencies and training grant program began in fiscal year 1981 and you plan to terminate it after three years of operation. What is your rationale?

Answer: Funding for the general dentistry residency and training grant program began in fiscal year 1978 under authority of Section 786 (b) of the Health Professions Educational Assistance Act of 1976. The Administration is aware of the importance of advanced clinical training for general dentists, and of the accomplishments of this training grant program. However, in considering current fiscal resources and in establishing program priorities, the Administration has determined that the program needs for assuring an adequate supply of primary medical care providers is of a higher priority than support for similar program in general dentistry.

Question. I note that although you plan to increase the total number of family medicine graduate program project grants in 1984, you will be reducing the average award by about $18,000. Can you tell us how this will affect the programs you are funding?

Answer. Basically, the programs being funded would be expected to assume a higher percentage of total program costs within the current budgetary constraints. To the extent possible, we are promoting increased sharing of financial responsibility with the institutions involved. We are hopeful this will not have serious impact on the program.

Question: Your justifications indicate that your family medicine graduate program will provide $19,238,000 in 1984 and support 4,928 residency positions. On the other hand your general internal medicine and pediatrics program will obligate $12,040,000 and support only 972 total residents. This means the cost per resident under the family medicine program in 1984 will be $3,904 while under the internal medicine and pediatrics program it will cost $12,387 per resident next year. Can you explain why one program is so much more expensive than the other?

Answer. These programs are principally institutional support programs. In addition they provide last Federal dollar stipend support to residents. Partial, rather than full, student support is usually provided thus per student cost comparisons are misleading.

FAMILY MEDICINE

Question: You are proposing a 13 percent reduction in your program to support departments of family medicine at medical schools yet your justification narrative indicates that "family medicine units lack the necessary resources to provide a comprehensive approach to the production of family physicians". Does your proposed cut mean that other resources are becoming available or have you simply downgraded the importance of family medicine in the general scheme of things?

Answer: The reduction neither means the downgrading of the importance of family medicine nor that other resources and becoming available. It is simply a matter of competing federal dollars in a tight budget. As you are aware, there are many competing demands for high national priority needs.

Question: I note that the number of family medicine department projects would stay the same in 1984 but that the number of individuals participating in these projects would decline by about 16 percent. Is this decision to reduce the number of participants based on some sort of study of the national need for family medicine practitioners or a concrete indication that the slack will be picked up elsewhere?

Answer: The reduction is neither based on a national study of the need for family medicine practitioners nor any indication that the slack will be picked up elsewhere. It is merely a proportional cut in trainees in relation to the reduction in dollars requested over what had been projected as appropriate Federal funding.

PREVENTIVE MEDICINE

Question: You propose to spend $1,055,000 on preventive medicine residencies next year to benefit 30 residents yet your budget narrative indicates a shortage of 1,750 preventive medicine physicians by 1990. At the rate you are going it would take 58 years to meet the shortage through this program. Why should we devote any

money to an effort that seems largely symbolic and will have little practical effect on the problem?

Answer: The Administration has a significant interest in the development of educational systems needed to produce physician personnel required to sustain the Federal initiatives in health promotion/disease prevention. We expect these funds to provide a stimulus to state and local governments and other entities to contribute to this endeavor. It is not our intent to provide for the support needed to meet total national needs.

Question: The cost per preventive medicine resident receiving Federal support is $35,167 — about ten times as much as you spend per family medicine resident and approximately three times the cost of supporting each internal medicine resident. Why is the program so terribly costly?

Answer: These programs are principally institutional support programs with student assistance costs not always proportionally allocated. Thus it is difficult to make accurate comparisons.

HEALTH PROFESSIONS ANALYTICAL STUDIES AND REPORTS

Question: You are requesting $3,612,000 for health professions analytical studies and reports in fiscal year 1984. How much will be spent on identifying, designating, de-designating, and reviewing health professions shortage areas throughout the United States?

Answer: The identification, designation and review of health professions shortage areas is a labor intensive effort which is performed almost entirely in-house by Bureau of Health Professions staff on a continuing basis. Analytical Studies and Reports funds are not expended directly in the designation review process. These funds are utilized, however, to support technical assistance to enhance State, local, and private sector participation in the designation process and to fund technical studies to improve the designation process and criteria, such as the current project to expand and refine mental health personnel shortage area designation criteria.

Question: How many shortage areas have been newly designated in each of the last three fiscal years?

Answer: Shortage area designation records are maintained by calendar year rather than fiscal year, and are available only for the calendar years 1981 and 1982. In 1981 there were 299 new designations. In 1982 there were 270 new designations.

Question: How many shortage areas have been de-designated in each of the past three fiscal years?

Answer: In calendar year 1981, there were 140 de-designations (withdrawals). In 1982 there were 39 de-designations.

Question. You indicate in your justifications that the increase of $650,000 requested for analytical studies and reports will provide for 3 additional contracts to be awarded. What work will be performed under these contracts?

Answer: The $650,000 increase over the FY 1983 budget would support a contract for activities aimed at identifying patterns of specialty training choices for specialties believed to be in short supply. Initial focus would be on family practitioners. The increase would also support a contract to accelerate the progress in integrating data from the National Sample Survey of Clinical Psychologists into the development of revised mental health manpower shortage area designation criteria. The third contract would support the National Sample Survey of Registered Nurses, a comprehensive report regarding the status of nursing personnel, which we attempt to update about every four years.

DISADVANTAGED ASSISTANCE

Question: You are requesting a total budget for disadvantaged assistance of $18,188,000 in the coming fiscal year. I note that your continuation grants will drop from 106 in 1983 to 9 in 1984 and that your new grants will increase from 9 in 1983 to 114 in 1984. Can you explain the reason for this dramatic shift?

Answer: Most of the disadvantaged assistance grants are funded for three-years. The level of appropriations has not increased, therefore, every third year of the program, a much greater amount of money for competitive applications, both new and renewal, becomes available than in the other two years.

Question: What proportion of your new grants in 1984 will be made to institutions that currently have no grants?

Answer: The proportion of new grants in 1984 that will be made to institutions which currently have no grants can only be estimated based on previous experience. In 1981, the last major grant award year, 89 of 155, or 57 percent of funded applications were from previously unfunded institutions. What this proportion will be in 1984 will depend on the quantity, and quality of new and renewal applications.

PODIATRIC SPECIALTY TRAINING

Question: You plan to spend $1,055,000 on podiatric speciality training in 1984, a program that does not currently exist. Why have you decided to initiate this particular program rather than a program in osteopathy or optometry, to give two examples of alternatives?

Answer: To the extent that limited financial and other resources permit, podiatric medicine should be considered a high priority with this program. The data provided below indicate the rationale for the priority:

* Approximately 73 percent of all counties in the U.S. do not have a podiatrist

* Podiatrists are the most unevenly distributed of any of the health professions (from Third Report to the President and Congress).

* Seventy-three percent of the students enrolled in podiatry colleges in academic year 1982-83 were from seven States (New York, Pennsylvania, Michigan, New

Jersey, California, Illinois and Ohio). The five long-established colleges are located in these States.

* Based on estimates for December 1980, fifty-eight percent of active podiatrists are practicing in these same seven States.

* Efforts by the Podiatry profession to break this continuing pattern of maldistribution have only been minimally successful. The visibility of Federal support to address this problem is needed now to assure improved access to foot care service throughout the Nation.

* In 1979 there were 8,340 active podiatrists in the U.S. An additional 1,203 podiatrists are necessary to bring the practioner-to-population ratio up to 1:28,000. This ratio represents the number of podiatrists needed to treat foot conditions typically seen by podiatrists.

* The number of active podiatrists per 100,000 population has increased from 3.4 in 1970 to 3.8 in 1977.

* By most measures of geographic maldistribution, podiatrists are among the most unevenly distributed of all health professionals. Graduates tend to locate near the school from which they received their training.

* By 1990 there potentially could be a short fall of 3,500 podiatrists which would require a 92 percent increase from the 1979 supply.

* In 1974, the average age for podiatrists was 51. This makes it difficult to substantially increase the supply of podiatrists because so many are leaving the work force each year.

* More podiatrists are also projected to be needed as the population becomes more aged.

ADVANCED NURSE TRAINING

Question: You are proposing a reduction in funding for advanced nurse training of over $12 million which would leave you with a $1.2 million program next year. The data on page 127 of your justifications indicates that the cost per nursing student under this program will increase from $5,145 in 1983 to $7,550 in 1984. Why don't you put your limited advanced nurse training dollars into the most cost beneficial programs next year so that you achieve the greatest results for the number of dollars made available? You seem to be going in exactly the opposite direction.

Answer: Cost benefit cannot be measured in terms of cost per student in this type of program, which provides institutional support to plan, develop and operate new programs at the graduate level. Planning is critical to sound program development and, at any given time, at least a third of the programs receiving support are in the

planning phase preparatory to the admission of students. These programs, once soundly developed, attract significant numbers of students and the cost/benefit ratio at that point is excellent.

Question: You indicate on page 129 of your justification that a portion of your nursing special projects budget will be spent on "initiating steps to avoid burn-out of nurses in emotionally and physically taxing types of work". Could you elaborate and tell us how much you plan to spend on this type of project in 1983 and in 1984?

Answer: One such project, "Demonstration Primary Care Clinic: Stress Management", building upon work completed in a previously funded grant, is in the review process. It requests $259,608 for a two year period beginning in FY 1984. The dollar levels for this activity are not yet known.

Question: You plan to terminate your professional nurse traineeship program next year. Your justifications indicate that special consideration is given under this program to nurse practitioners training to be midwives. Do we have an adequate supply of midwives in the United States at the present time and, if not, will the a lack caused by the termination of this program be picked up elsewhere?

Answer: Preliminary findings from a survey being conducted by the American College of Nurse Midwives indicates that there is brisk demand for midwives, although we have no opinion on whether demand outstrips supply. While we know of no other Federal programs in this area, we expect institutions to attempt to continue these programs.

HEALTH PROFESSIONS DIRECT OPERATIONS

Question: On page 136 of your justifications you indicate that a portion of your $12,527,000 Health Professions Direct Operations budget for fiscal year 1984 will be used to pay for the cost of conducting National Advisory Council and peer review meetings. In view of your proposed cutbacks in a number of programs I would assume that these costs will fall dramatically. Can you tell us how much you are currently spending for this purpose and how much you intend to spend in 1984?

Answer: We estimate our peer review and National Advisory costs for fiscal year 1983 to be $405,000. With program reductions in fiscal year 1984, our estimate for these costs in 1984 will be somewhat less.

HEALTH SYSTEMS AGENCIES

Question: Your rationale for recommending the elimination of all Federal funding for Health Systems Agencies (HSA's) in fiscal year 1984 is that this will "reduce the national health regulatory burden on States and localities and...promote the effective functioning of private market forces in the health care sector".

However an article in the February 21 Miami Herald states that in South Florida, where the HSA system has already been phased out, builders filed more applications for new hospitals last year than during the previous decade. A Miami Beach legislator was quoted as saying "The major enemy of health planning and cost containment has always been the hospitals. Now there are fewer barriers to the

rapacity of organized medicine. It is probably going to cost people more money for worse care."

Question: How do you respond to that charge?

Answer: Our position is that it is inappropriate for the Federal government to regulate nationally the provision of health care, because each State locality has a unique set of health care needs and health delivery systems. Some areas are overbedded, others are underbedded. We believe that private market forces and competitions will have a greater influence on ameliorating health care costs on the local level than will a national regulatory program. The recently enacted Social Security amendments of 1983 provide for a prospective reimbursement system which sets fixed rate reimbursements under Medicare. That new legislation should give health facilities an additional incentive to control capital investment in unneeded facilities.

Question: Has there been any effort within the Department to evaluate to what extent the elimination of Federal HSA support will affect the rate of inflation in medical care costs?

Answer: In response to your question, the answer is no. We do not believe that the existence of HSAs has affected the current rate of inflation of medical care costs, and, therefore, their elimination won't have any effect either.

Question: In proposing the elimination of all funding for Health Maintenance Organization Management Training and Technical Assistance you state on page 144 of your justification that "existing in-house staff will be sufficient to provide needed technical assistance to developing and operating HMOs." How many in-house staff are you currently devoting to this activity and what will be the staffing level next year?

Answer: In both FY 1983 and FY 1984, at least nine (9) full-time permanent positions will be devoted to this activity.

DEBT COLLECTION

Question: On page 145 of your justifications you indicate that you monitor $1.2 billion in health facility loans and loan guarantees to minimize Federal default liability. What part of this loan portfolio is currently in default and what plans do you have to collect the amount owed the government?

Answer: There are three (3) Direct Loans in default with outstanding balances of $9.2 million and five (5) Guaranteed Loans in default with outstanding balances of $28.9 million. When loans go into a default status, Bureau staff work with the institution in any attempt to negotiate an acceptable attempt to provide technical assistance to the facility to help it maintain a satisfactory loan repayment schedule. I would add that technical assistance is provided to facilities with potential loan repayment problems to prevent or reduce the possibility for default.

Question: How many staff are currently devoted to this activity and how many staff years are included for this purpose in your 1984 budget request?

Answer: We estimate about 18 staff years are devoted to this activity currently and our FY 1984 budget request will allow us to continue at that level.

Question: Can you explain why a reduction of 55 positions is expected to result in savings of $6,480,000 in Health Resources and Services Administration program management while a cut of 130 positions in your Bureau of Health Maintenance Organizations and Resources Development is projected to save only $6,025,000?

Answer: The savings of $6,480,000 in the Health Resources and Services Program Management activity is as a result of the reduction of 55 full-time permanent positions and the elimination of 35 other-than-permanent positions. In addition, a substantial part of the Program Management activity budget has been used in the past to support centralized payments for the Bureau of Health Professions and Bureau of Health Maintenance Organizations and Resources Development activities, for which a proportionate reduction is reflected in the Program Management activity budget request for fiscal year 1984, based on the position reductions in these two activities.

MEDICAL FACILITIES GUARANTEE AND LOAN FUND

Question: You are requesting a level budget of $32 million for the Medical Facilities Guarantee and Loan Fund next year yet you will experience a drop of $1.3 million in obligations according to page 160 of your justifications. In view of this projected drop in obligations as well as an estimated unobligated balance at the end of 1983 of $48,343,000, why couldn't you take a modest reduction in this account?

Answer: The request of $32 million in the Medical Facilities Guarantee and Loan Fund is required to meet our statutory obligations for interest subsidies in FY 1984. The estimated FY 1983 payments of $31.9 million leave virtually no carry-over balance in the interest subsidy account. The estimated obligations, however, include all transactions in the Loan Fund. Some of these transactions are in other accounts with the Fund. The balance of $48,343,000, that we estimate will be in the Fund at the end of FY 1983, is the sum of the other two parts of the Fund - approximately $4.3 million in the Direct Loan Fund and approximately $44 million maintained to cover defaults.

Question: You are projecting $17,979,000 will be paid out of the Health Maintenance Organizations Loan and Loan Guarantee Fund in the current year for guarantee loans default payments. There were no such payments last year and you anticipate none in fiscal year 1984. What happened in the current year to activate this dormant account?

Answer: As a result of discussions with Office of Management and Budget representatives since the initial preparation of the FY 1984 budget request, we have determined that an error exists in the budget presentation of the Health Maintenance Organizations Loan and Loan Guarantee Fund. The $17.9 million represents the par value of the defaulted loans for 13 Health Maintenance Organizations held by the Federal Financing Bank (FFB) as of December 31, 1982. The FY 1982 Supplemental Appropriation of $17.5 million was used in November 1982 to repurchase those notes. The difference represents the discount taken at the time of original sale to FFB. In previous years, no funds were requested to repurchase defaulted notes from

FFB. A request for a Supplemental Appropriation is submitted at the end of the First Quarter to cover losses or to repurchase any defaulted notes held by the FFB, which occurred in the previous calendar year. We will not know what our FY 1984 needs will be, if any, until December 1983.

Question: You also show an unusual level of activity in disbursements to the Federal Financing Bank this year -- total disbursements of $17.5 million compared with no disbursements in 1982 and projected expenditures of $1.5 million next year. Can you explain the current high level of activity in this area?

Answer: As I indicated previously, the high level of activity was occasioned by the FY 1982 Supplemental Appropriation of $17.5 million which represents disbursements to the FFB for repurchase of defaulted notes and should have been labeled as such in the budget presentation. The estimated $1.5 million in FY 1984 represents repayments of principal by borrowers on notes currently held by the FFB.

Question: Last year the Committee included language in its report calling on the Department to submit its views to the Committee regarding the administrative flexibility that currently exists to target funding under the Health Education Assistance Loan program to certain specialties. The Department's response was that it would respond to questions on this subject during the course of the 1984 Congressional hearings. I would expect you to be willing to respond to questions on any subject that falls within your jurisdiction but this isn't what the Committee asked for. Why haven't you submitted the requested report?

Answer: The report was forwarded to Congress on April 4, 1983.

Question: On page 184 of your justifications you state that "private lending institutions have disbursed $166 million in loans" since the Health Education Assistance Loan program began in 1979 and that private lending institutions "will make $175 million additional loans to 17,500 students" during fiscal year 1984. How is it that more loan dollars will be disbursed in the next fiscal year than over the life of the program thus far?

Answer: The HEAL program is growing very rapidly after a somewhat slow start. The rapid growth has come about as a result of more financial institutions loaning out their funds; more students becoming familiar with the program and fewer alternative sources of funds available for student aid. In its first year of operations FY 1979 disbursements totalled only $9,000,000. During FY 1982 disbursements totalled $93,000,000 which is more than half the $166,000,000 disbursed from the beginning of the program through the end of FY 1982. At present in FY 1983 we are running at double the rate for the same months last year.

ASSISTANT SECRETARY FOR HEALTH

STATEMENT OF DR. EDWARD N. BRANDT, JR., ASSISTANT SECRETARY FOR HEALTH

ACCOMPANIED BY:

GLENNA M. CROOKS, PH. D., DEPUTY ASSISTANT SECRETARY FOR HEALTH PLANNING AND EVALUATION

MARJORY E. MECKLENBURG, DEPUTY ASSISTANT SECRETARY FOR POPULATION AFFAIRS AND DIRECTOR, OFFICE OF ADOLESCENT PREGNANCY PROGRAMS

DR. MANNING FEINLEIB, DIRECTOR, NATIONAL CENTER FOR HEALTH STATISTICS

JOHN E. MARSHALL, PH. D., DIRECTOR, NATIONAL CENTER FOR HEALTH SERVICES RESEARCH

DR. J. MICHAEL McGINNIS, DEPUTY ASSISTANT SECRETARY FOR HEALTH (DISEASE PREVENTION AND HEALTH PROMOTION)

DR. JOANNE LUOTO, DIRECTOR, OFFICE ON SMOKING AND HEALTH

JOHN D. MAHONEY, CHIEF, BUDGET BRANCH, PHS

ANTHONY L. ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET

PREPARED STATEMENT

Senator WEICKER. The next witness this morning is Dr. Edward Brandt, Assistant Secretary for Health.

And Dr. Brandt will testify on a number of questions for the Public Health Service management and proposed health block grant appropriation and retirement pay and medical benefits for Public Health Service commissioned officers.

Dr. Brandt, welcome. Your statement in its entirety will be included in the record.

Please introduce those that accompany you at the table, and proceed any way you see fit.

[The statement follows:]

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STATEMENT OF EDWARD N. BRANDT, JR.

I appreciate the opportunity to appear here today to discuss the budget request for the three appropriations in the Office of the Assistant Secretary for Health. The Public Health Service Management appropriation request of $122.9 million includes funding for a number of special health programs and supports the overall program direction of the Public Health Service. The Health Block Grant appropriation request of approximately $1.4 billion includes funds for the four block grants. Finally, we are requesting $78.9 million for Retirement Pay and Medical Benefits for Commissioned Officers.

PUBLIC HEALTH SERVICE MANAGEMENT

I would like to describe several of the accomplishments and contributions made by the programs in these appropriations and share with you our plans for Fiscal Year 1984.

The accomplishments and unique missions of the National Center for Health Services Research and the National Center for Health Statistics qualify them as true national resources. The research, data collection, and analysis supported by these Centers is essential to an understanding of the functioning of our health care system and its rapidly rising costs. It is only through improvements in our understanding of the health industry and the behavior of the health services consumer that we can hope to increase the effectiveness of the health care system while controlling its costs.

Knowledge gained through studies supported by the National Center for Health Services Research forms the basis for two of the Administration's proposals for significantly reducing medical care costs without diminishing the quality of health care. The Center funded the development of the diagnostic related group concept (DRG) which underlies the prospective reimbursement method for controlling Medicare expenditures. Hospital reimbursement for certain groups of medical procedures would be based on predetermined rates. Hospitals experiencing lower costs on a specific procedure or DRG would be entitled to the difference between the actual cost of the procedure and the established rate. Hospitals with higher costs would have to absorb the cost difference and could not pass the unreimbursed costs on to Medicare beneficiaries. This system would have the effect of rewarding efficient providers and penalizing less efficient providers.

Another National Center for Health Services Research study indicated that $31 billion in Federal and State tax revenues is lost annually by excluding all employer-paid health premiums from the taxable income of workers. Based on these findings, the Administration is proposing to tax a portion of these premiums, thereby producing estimated additional tax revenues of $2.3 billion in 1984 and encouraging individuals and employers to seek less expensive forms of health insurance.

In 1984, we will continue ongoing studies of the role of market forces in order to identify and analyze incentives and strategies that might be used to make the health care market more competitive and efficient. We will also give high priority to continuing health

services research that is consistent with my overall emphasis on prevention and health promotion and to the analysis of new, controversial or possibly cost-ineffective medical technologies.

The National Center for Health Statistics is the repository for basic health data on vital events such as births, deaths, and marriages as well as a variety of special data on the health status of the U.S. population and the use and cost of the health care system. In addition to many components of the Public Health Service, other Federal agencies, States, and researchers both within and outside the U.S. are users of these data. Publications of the Center include the Department's comprehensive annual health report to Congress, entitled Health, United States. Our 1984 budget request will permit us to continue on-going data collection activities as well as all annual and periodic surveys and will provide funding for a supplement to the National Health Interview Survey to focus on the elderly. In addition, the request will provide funds to supplement the work of the Bureau of the Census for the redesign of population-based national surveys to reflect the decennial Census.

One of the major priorities of the Public Health Service is prevention of disease. Five major prevention programs -- Adolescent Family Life, Smoking and Health, Health Information and Health Promotion, National Youth Sports and Physical Fitness and Sports -- operate under my direct supervision. The budget request for these programs of $29.8 million represents an increase of $5.5 million in 1984.

There is still considerable concern about the continuing trend of adolescent sexual activity at younger ages and the subsequent increase in teenage pregnancies. To address this concern in Fiscal Year 1984 we are requesting $16.3 million which is an increase of $2.9 million over 1983. These funds will be used to support additional model demonstration projects that provide care and prevention services to pregnant adolescents and adolescent parents. These model approaches will emphasize the participation of family members in dealing with these problems and will also encourage consideration of adoption as a viable alternative. Research projects will be supported with the goal of building a sound knowledge base for making policy decisions and providing services. Our hope is that certain approaches will emerge from the various experimental models that can be employed as positive interventions in reversing the high incidence of unplanned pregnancy among teenagers.

Cigarette smoking remains the major preventable cause of premature death and disability. Research has also led to the conclusion that smoking is the most widespread example of drug dependence in this country. We have recently published this fact through a pamphlet released by the Office on Smoking and Health entitled "Why People Smoke Cigarettes." It is important to give widespread attention to such findings because we have found that declines in annual per capita consumption have occurred during periods of increased publicity on the health hazards of cigarette smoking. In recognition of this relationship, $400,000 is being requested to expand our currently operating public information media campaigns. It is imperative that cigarette smokers realize that while they are at greater risk from certain diseases while they smoke, the level of

risk will decrease if they stop smoking. In 1984 we are also requesting an increase of $1 million to undertake a survey to re-examine the smoking behavior of both adults and young people. The most recent studies were conducted eight years ago for adults and four years ago for young people. The data to be collected will provide direction for prevention efforts and will be used extensively by the scientific community for the conduct of biomedical and behavioral research. This information will also be used for the 1985 and 1986 annual Surgeon General's report to Congress.

The Office of Disease Prevention and Health Promotion is the focal point for overall coordination of Public Health Service prevention efforts and serves as a catalyst to encourage additional prevention activities. For example, the Office had the lead responsibility for developing the 15 measurable health objectives for 1990 which are now being implemented by the health agencies. In addition to managing the PHS activities, the office collaborates with other components of the Department, other government agencies and public and private groups involved in disease prevention and health promotion. With a minimum investment of Federal funds, we have succeeded in encouraging voluntary organizations to increase their support of activities to promote good health practices by their members. Cooperative agreements have been signed with the Red Cross, YMCA, Urban League and the National Coalition of Hispanic Mental Health and Human Service Organizations which will enable us to reach thousands of people through the local chapters of these groups. The 1984 budget will permit us to initiate five new cooperative agreements with other organizations. In addition, the increase of $1.2 million for the health promotion program will permit the National Health Information Clearinghouse to increase its capacity to respond to public inquiries, will expand the National Health Promotion Media Campaign to focus on the elderly and will continue developing stronger prevention monitoring capabilities as well as increasing scientific support and technical assistance related to disease prevention and health promotion.

The 1984 budget request will also continue our efforts to encourage Americans to participate in regular physical fitness and sports activities, and will enable us to provide staff support for the President's Council on Physical Fitness and Sports. Federal staff efforts generate approximately $35 million annually in financial support within the private sector for physical fitness activities. Our 1984 budget request also includes $5.8 million for the National Youth Sports Program which was previously administered by the Office of Community Services. This program consists of a single grant to the National Collegiate Athletic Association which supports a comprehensive developmental and instructional sports program for low income youth at 138 member colleges and universities. The primary goal of the program is to enable the participants to earn and learn self respect through sports participation. In addition to the sports program, counseling is provided on drug abuse prevention, job responsibilities and opportunities, and good study and nutrition practices. The 1984 request is the same as the 1983 level and will provide the resources to continue to serve approximately 50,000 boys and girls between the ages of 10 and 18.

We are requesting $19 million for the management and direction of the Public Health Service, an organization with resources totalling

45,000 employees and an estimated budget of $7.7 billion in 1984. As a result of various consolidations and management actions we have reduced the staffing of this activity by 34 percent or 167 positions since 1981. The 1984 request will permit this office to continue an effective overall management capability for administering PHS and OASH programs.

The 1984 budget for PHS proposes to eliminate a total of 844 positions associated primarily with the consolidation of categorical primary care programs into a block grant, the elimination of the health planning program, and a diminishing Federal role in health professions training. We estimate that it will be necessary to involuntarily separate approximately 550 employees and are requesting $9.7 million for costs related to these separations. As in past years, funds for these termination expenses are requested in my office to facilitate administrative control of the funds within PHS.

GRANTS TO STATES FOR HEALTH

The 1984 request includes block grant funding for the Preventive Health and Health Services, Alcohol and Drug Abuse and Mental Health Services, Maternal and Child Health and Primary Care programs. Three of these grants were successfully initiated in Fiscal Year 1982 with mandatory implementation by the States in Fiscal Year 1983. The fourth health block grant, for primary care programs, is authorized in Fiscal Year 1983 with optional participation through Fiscal Year 1984. At the present time there are certain disincentives which discourage participation in the Primary Care block grant. For example, the current law requires states and territories to meet a minimum matching requirement of 20 percent in 1983 and 33 percent in 1984. As a result of these restrictions only one state and one territory have applied for this block grant to date. The Administration's proposed legislation would eliminate these disincentives and would make participation in the primary care block grant more attractive. Furthermore, we plan to consolidate the Migrant Health Centers, Black Lung Clinics, and the Family Planning program into the Primary Care block grant.

The Fiscal Year 1984 funding level for the four grants is approximately $1.4 billion. We are requesting that funding for these grants be included in my office in order to establish a single administrative unit for all block grants. This will streamline administrative procedures, simplify State/Federal contacts, and assure maximum flexibility to the States in administering the grants.

RETIREMENT PAY AND MEDICAL BENEFITS FOR COMMISSIONED OFFICERS

This appropriation funds retirement payments to Public Health Service Commissioned Officers, payments to survivors of officers who elected to receive a reduced annuity, and the costs of medical care of active duty and retired officers, their dependents and survivors.

In Fiscal Year 1984 a new policy will be implemented to collect a pro rata share of indirect costs associated with the detail of an active duty officer outside of the Department of Health and Human

Services. The request of $78.9 million assumes anticipated collections of $6.3 million. The 1984 request does not propose a May 1984 cost-of-living increase. This is in accordance with the Administration's policy to eliminate the cost of living adjustment for various Federal retirement plans.

I will be happy to answer any questions you may have.

Biography of Edward N. Brandt, Jr.

Edward N. Brandt Jr. was sworn in May 14, 1981, as assistant secretary for health, Department of Health and Human Services. Dr. Brandt was nominated by President Reagan Feb. 13, 1981, and confirmed by the Senate May 4, 1981.

Before joining HHS, Dr. Brandt, a physician, was associated with the University of Texas. Since 1977, he had been vice chancellor for health affairs for the university system, based in Austin. From 1970 to 1977, he was dean of the graduate school, dean of medicine and executive dean of the University of Texas Medical Branch in Galveston. He had also served since 1970 as professor in the university's departments of preventive medicine and family medicine. From 1962 to 1970 Dr. Brandt was at the University of Oklahoma Medical Center, first as director of the Medical Research Computer Center and later as associate dean and associate director of the medical center.

As assistant secretary for health, Dr. Brandt directs the activities of the Public Health Service, which includes the Alcohol, Drug Abuse and Mental Health Administration; the Centers for Disease Control; the Food and Drug Administration; the Health Resources and Services Administration; and the National Institutes of Health.

Dr. Brandt provides policy guidance for other HHS health programs including the Health Care Financing Administration, which administers Medicare and Medicaid. He also maintains relationships with other governmental and private agencies concerned with health. He advises and assists the Secretary on health policy and on all health-related activities of the department.

Dr. Brandt was born July 3, 1933, in Oklahoma City, Okla. He received his B.S. degree in mathematics from the University of Oklahoma in 1954 and an M.S. degree in mathematics from Oklahoma State University in 1955. He received his M.D. in 1960 from the University of Oklahoma Medical Center and a Ph.D. in biostatistics from the same university in 1963. Dr. Brandt served his internship at the Veterans Administration Hospital in Oklahoma City and was an internal medicine resident at the University of Oklahoma Medical Center.

Dr. Brandt is the U.S. member of the Executive Board of the World Health Organization and is the U.S. delegate to the Pan American Health Organization. He has been active in various committees of the American Medical Association, Texas Medical Association and the American Association of Medical Colleges. At the time of his confirmation as assistant secretary for health, he was serving as chairman of the AMA's section on medical schools. He is also a member of the American Academy of Family Physicians' Commission on Legislation and Governmental Affairs. He has served on many boards, committees and foundations and holds memberships in a number of honorary and professional societies.

Dr. Brandt has published extensively and has made significant contributions to the professional literature throughout the entire range of health and statistical issues.

Dr. Brandt and his wife, the former Patricia Lawson, have three sons: Patrick James, Edward N. III and Rex Carlin.

October 1982

INTRODUCTION OF ASSOCIATES

Dr. BRANDT. Thank you very much, Mr. Chairman. It is a pleasure to be here.

Let me introduce the people at the table.

Mr. Itteilag who was introduced before, Deputy Assistant Secretary for Budget in the Department.

On my left, John Mahoney who is the Chief of the Budget Branch for the Public Health Service.

I would like just to take a moment, if it is agreeable with you, Mr. Chairman, to summarize very quickly our request for the Office of the Assistant Secretary of Health.

Our budget includes three appropriations:

The Public Health Service management appropriation of $122.9 million which includes funding for a number of special health programs, and in addition, supports the overall program direction of the Public Health Service;

The health block grant appropriation request of approximately $1.4 billion which includes funds for four health block grants;

And finally, we are requesting $78.9 million for retirement pay and medical benefits for commissioned officers of the Public Health Service.

SPECIAL HEALTH PROGRAMS

I think it might be worthwhile to take just a moment to summarize the special health programs for which we are requesting money.

They include the National Center for Health Services Research which supports many unique research projects to further our understanding of the health services delivery systems. Knowledge gained through studies supported by this Center provided the basis for two of the administration's proposals this year—first, the concept of prospective rate setting for medicare payments based upon diagnostic related groups. The second proposal is to tax a portion of employer-paid health premiums in order to recoup some of the $31 million in Federal and State tax revenues that are lost each year by excluding all employer-paid health premiums from taxable income.

Our budget also supports the National Center for Health Statistics, which is the repository for basic health data on vital events such as births, deaths, and marriages as well as a variety of special data such as nutritional status, use of ambulatory care, and other components of our health care system. This request also funds five major prevention programs—adolescent family life, smoking and health, health information and health promotion, national youth sports, and physical fitness and sports.

HEALTH BLOCK GRANTS

With that, sir, I will close with just one other statement regarding the block grants. The primary care block grant, as you know, was passed by the Congress, but was limited only to the community health centers and

included a number of disincentives which discourage the States from participating in that block grant.

The administration's proposed legislation would eliminate those disincentives and, in addition, would propose to consolidate within that block the migrant health program, black lung clinics, and the family planning program. This proposal would provide a comprehensive primary care block grant for the States to administer.

I, and my colleagues—the people responsible for each of these programs who are here today—would be pleased to answer any of your questions.

Senator WEICKER. In addition to placing the primary care block grant under your jurisdiction, I understand legislation will be proposed to fund family planning, migrant health and black lung activities under this block grant.

In fiscal year 1983, the combined appropriations for these three programs is $165.3 million. Yet, the only discussion in your justification of these activities is one paragraph of the footnote on page 198.

Can you explain why there is no substantive information offered on the performance of these programs and why there is no discussion of the merits of placing them within the proposed block grant which was, incidentally, rejected last year?

Dr. BRANDT. Well, I can't explain why the justification is as brief as it is, but I will be happy to expand on the proposal now if you would like.

One of the problems last year was a misunderstanding of what we were proposing to do. The core of health services under our current system of delivering health care is primary care. If, in fact, we are going to develop a system that provides care for the underserved people in this country, we must build it around a system of primary care.

The programs beyond community health centers that we have proposed for the primary care block, include family planning, which is a primary care service and one, therefore, that should be offered along with other kinds of care. It includes migrant health which is another primary care program aimed at a specific population segment in this country. Finally it includes black lung services which again should be offered in conjunction with other components of primary care.

We believe that this approach will provide total comprehensive care rather than the segmented care which would require people to receive total care through a variety of sites, and a variety of different providers.

As a specific example, it is very clear that young women who are becoming sexually active should be vaccinated against pertussis. German measles still cause a number of birth defects in this country. Yet, in our family planning clinics, we cannot provide vaccinations. They have to go to family planning clinics to receive care for reproductive aspects and go someplace else to receive other kinds of prenatal care.

We believe that by combining these services, we can further reduce the infant mortality rate and reduce the number of birth defects in this country.

That is the reason why we have proposed this program.

Senator WEICKER. If this block grant expansion is not approved, what will your request for family planning, migrant health, and black lung programs be?

Dr. BRANDT. Do you mean in terms of a budget request?

Senator WEICKER. Yes.

Dr. BRANDT. I don't know precisely, but we will request them in the block grant.

Senator WEICKER. Well, I have got to have that information here. Again, I am getting right back to where we were before. I am trying to run an Appropriations Committee here, not an authorizing committee.

Dr. BRANDT. Well, our current budget proposal is based on providing funds at the 1983 level for each of those three programs—the 1983 level prior to the passage of the recently enacted jobs bill.

ADMINISTRATION OF BLOCK GRANTS

Senator WEICKER. The budget once again proposes putting the health block grants under your umbrella.

Now, you have nearly a $1.4 billion appropriation request for four major block grants. And there is no discussion in the budget of their past operations, accomplishments, State experience with these programs or information on a number of actual persons served.

Now, we are talking about preventive health, alcohol, drug abuse, and mental health, primary care; and maternal and child health. How are we going to make an informed decision about these programs, judging the effect of the block grants, without that kind of information?

Dr. BRANDT. Well, let me explain our proposal for the administration of the block grants.

In the first place, the block grant activities provided by my office would be solely an administrative function. We are not talking about provision of technical assistance to the States and to the localities. That will still be done by Public Health Service personnel located in the appropriate agencies.

Rather, our request is simply to provide for some administrative simplification which will streamline administrative functions now provided by several agencies.

The States would only deal with one office on administrative matters instead of several as they currently have to do.

The concept behind the block grants, of course, was to basically ask the question if you are attempting to serve people, who is doing it? The facts are that those providing services are local personnel located in the States and the localities.

The block grants permit the States some flexibility in best meeting the needs of their people rather than assuming that every State has exactly the same needs which have to be dealt with in exactly the same way.

We have provided the States with those funds, and reports are coming in which provide us with information. But the block grants are only 1 year old, essentially. We are only in the second year of those three blocks that are in operation.

The primary care block, of course, has not been accepted in its present form.

Senator WEICKER. Senator Burdick.

REDUCTION IN NURSING PROGRAMS

Senator BURDICK. Thank you, Mr. Chairman.

Dr. Brandt, the President's budget recommends approximately a 75-percent funding reduction for nursing programs, including complete elimination of student loan assistance, research projects, fellowships, and professional traineeships. Under this administration, these programs have already been slashed by more than 50 percent.

Isn't it fair to say that the nursing programs have already absorbed huge cuts and have carried their full burden of budget reductions?

Dr. BRANDT. I think, Senator Burdick, that one has to ask the question: What is the purpose of providing funding for those programs? The initial purpose for all of the health professions program was to meet a need, that need being defined as a shortage of health care professionals.

Every responsible group that I am aware of which has studied the problem, including most recently the Institute of Medicine, has concluded that there is no shortage of nurses in the aggregate.

There are three problems that they identify specifically:

The first is the distribution of nurses, which they believe is primarily a function of working conditions, pay, and other issues outside of the Federal domain.

Second, there is a need for training certain nurse specialists. And we have funds in there to accomplish that.

And third, they examined methods to improve the level of nursing care in this country through nursing research and other approaches.

We, therefore, are in agreement with the statement that in the aggregate, the nursing supply is adequate. We agree with the Institute of Medicine that working conditions and other similar stimuli are perhaps the most effective approach to obtaining better geographical distribution than we currently have. However, I do not think that it is appropriate for the Federal Government to tell the hospital what to pay their nurses or what shifts they should work.

NURSING EDUCATION FUNDS

Senator BURDICK. Doctor, you mentioned the Institute of Medicine. The 1983 Institute of Medicine study into nursing and nursing education, which was conducted at the request of Congress, cites the need for fellowships, loans, and graduate-level programs to expand the number of nurses with skills commensurate with the growing complexity of care in many health centers.

The report also calls for RN's with high-quality graduate education, a scarce national resource.

In light of IOM's recommendation, the funding of nursing education support efforts at the 1981 level of about $80 million, how do you justify the administration request for only $13 million for the various nursing programs?

Dr. BRANDT. Well, in the first place, of course, the report came out subsequent to our development of this budget request. But we believe the lines of the budget request are consistent with that report.

As I pointed out to you——

Senator BURDICK. That we are here now?

Dr. BRANDT. We are here now, that is correct.

As Dr. Graham testified just a few moments ago, the level of funding that the IOM recommended was by their own admission, an ideal funding level.

We are not in an ideal economic situation at the present time and are attempting to balance a number of competing interests.

We agree with the major thrust of the IOM. We do believe that it is necessary to continue to develop more nurse specialists, people at the graduate level, and are prepared to assist schools in developing those kinds of activities.

In addition, the nursing student loan program, which is administered by the schools, is still in operation with money that is available in the revolving funds.

Senator BURDICK. Don't you really think that a cut from $80 to $13 million in 1 year is pretty drastic?

Dr. BRANDT. It is consistent, of course, with the President's fiscal year 1983 request. That is, our budget objective over the past 2 to 3 years in our requests have been consistent.

NURSING SHORTAGE IN DISADVANTAGED AREAS

Senator BURDICK. The administration does acknowledge that the Nation's health care system continues to experience a nursing shortage in economically disadvantaged areas. Why is the administration requesting that the special project program which specifically addresses this problem be funded at only half the authorized level of $11 million?

Dr. BRANDT. We believe in the first place that a lot of the problems have already been solved. And I think, Senator Burdick, that we are proposing an acceptable reduction.

As a matter of fact, the fiscal year 1983 level is $6.3 million. We are proposing $6 million in fiscal year 1984.

Senator BURDICK. Well, amend it, then, $6.3 as against $11 million.

Mr. MAHONEY. The $11 million is the fiscal year 1984 authorization. The $6.3 million is the amount that Congress appropriated in 1983.

Senator BURDICK. That's OK with me. It still is $11 million.

Dr. BRANDT. Well, except we only have available to us to spend $6.3 million this year.

Senator BURDICK. That's under the budget.

Dr. BRANDT. Under the appropriation by Congress.

Senator BURDICK. The American Nurses' Association says that the greatest need in nursing today is for nurses with advanced training. That makes a lot of sense when you think about the sophisticated nursing and medical care that is required these days.

Clearly, we need highly trained professional nurses to work with patients with things like bone transplants, burn therapy, neurosurgery, and cardiac surgery. All of these require 24 hour nursing care that is very sophisticated.

Moreover, we have good evidence saying there are shortages of RN's with this type of scientific training. How can you possibly justify an advance training program which is sharply cut back and will provide a total of eight awards?

Dr. BRANDT. Our program has been to assist institutions to establish these programs. And like all other educational activities that I am aware of—and I have been an educator all my life—the institutions slowly begin to pick up these programs that demonstrate their usefulness.

We believe that the institutions will meet that kind of responsibility and will, in fact, begin to educate nurses in these areas.

ELIMINATION OF NURSE TRAINEESHIPS

Senator BURDICK. How can you justify asking for the elimination of the professional traineeship program which is designed to support students in graduate school?

Dr. BRANDT. Well, again, it is a matter of defining the highest priorities in a time of economic limitations. We believe that we have identified those areas of highest priority, and that it will be possible through private institutional means to pay those kinds of fellowships.

Senator BURDICK. Well, in the interests of time, Mr. Chairman, I wonder if we can get a response to some additional questions from the doctor and make that a part of the record when the responses come in.

They refer to the administration's proposal to eliminate nursing research projects and fellowships. And there are about eight categories. And I would like to make the categories now part of the record and the answers to be supplied.

Senator WEICKER. So ordered.

Dr. BRANDT. Yes, sir, we will certainly do that.

Senator BURDICK. Thank you, doctor.

[The information follows:]

FUNDING FOR EIGHT NURSING CATEGORIES

Nurse	1983 current estimate	1984 request	Increase or decrease
Advanced nurse training	$13,260,000	$1,208,000	-$12,052,000
Nurse practitioner	11,760,000	6,041,000	-5,719,000
Special projects	6,333,000	5,979,000	-354,000
Professional traineeships	9,600,000		-9,600,000
Fellowships	960,000		-960,000
Research grants	5,000,000		-5,000,000
Nurse student loans	860,000		-860,000
Nurse loan cancellations	750,000		-750,000
Total	48,523,000	13,228,000	-35,295,000

SURVEY ON SMOKING AND HEALTH

Senator WEICKER. Your budget requests an increase of $1 million for a survey on smoking. When was the last survey performed?

In a tight budget year, why do we need a survey now?

Dr. BRANDT. This survey will include both teenagers and adults to look at not only smoking habits, but also attitudes toward smoking by both teenagers and adults.

The last survey that was done for teenagers was 4 years ago and for adults 8 years ago. We believe it is important to do a survey now since cigarette smoking is still the leading preventable cause of death in this country. We are going to attempt to educate people so they will not begin smoking, or will quit smoking.

It is important that we understand why people smoke and what their attitudes are toward smoking so that we can target educational activities in that direction.

Senator WEICKER. The administration budgetary request of this year provides for a tobacco subsidy?

Dr. BRANDT. I do not know, sir.

ADOLESCENT FAMILY LIFE REQUEST

Senator WEICKER. Well, let me say this: I will tell you exactly what I am going to do with that $1 million. If the administration has no request for a tobacco subsidy, I will support your $1 million. If they do have it in there, I am not going to waste $1 million because I couldn't agree with you more in what you are saying.

I am not going down two roads at the same time.

Why do you continue to ask for a $16 million appropriation for adolescent family life program which is an increase of almost $3 million or 22 percent over last year's appropriation at a time when we are being asked to reduce the size of the Federal budget by eliminating programs such as health planning and cutting other activities to the tune of $1.6 billion?

Dr. BRANDT. The adolescent family life program was developed to attempt to deal with one of the major problems in this country—namely, a significant increase in adolescent sexual activity and adolescent pregnancy.

We were talking earlier, Mr. Chairman, about the infant mortality rate, and I failed to point out that one of the other factors which contributes to infant mortality is women who have babies at two ends of the age spectrum—namely, below the age of 17 and above the age of 35, both of which increase the risk.

The adolescent family life program supports model demonstration projects to identify successful approaches to addressing the problems of adolescent pregnancy and adolescent sexual activity. It is our hope that by funding some model programs, States and local communities can develop innovative approaches to deal with what we see as a health problem in the country affecting young people.

Senator WEICKER. I'm sorry, are you saying you are hoping States and local communities do this?

Dr. BRANDT. We are. It is our view that if we can develop successful demonstration projects the States and local communities will use those as models to develop their own programs. There are a number of private groups and voluntary groups of one kind or another that are trying to find a solution to this problem or at least trying to find some way of dealing with it.

Our approach is to use these funds to develop demonstration programs so that States and local communities will have something on which to base their activities when they begin addressing this problem.

SPECIAL FOCUS OF ADOLESCENT FAMILY LIFE

Senator WEICKER. What does the adolescent family life program do that is not done by family planning programs, title XIX, maternal and child health block grants, and title XX of the Social Security Act?

Dr. BRANDT. The adolescent family life model demonstration projects will offer ways to counsel young people, to help them deal with their pregnancy, and other aspects that are not covered by the other programs.

Mrs. Mecklenburg, the Director of the program, is here and she may want to elaborate.

Mrs. MECKLENBURG. The programs you mentioned have made significant contributions in addressing the adolescent pregnancy problem. The contributions by these programs should continue.

Unfortunately, when we look at the statistics and the difficulties that have arisen from increased early sexual activity, pregnancy, and VD, we see that the current programs are not sufficient to solve these problems, and we need to explore additional options.

In response, Congress and the administration initiated the adolescent family life program last year. It is a three-pronged approach to these difficult problems.

One is to improve prevention approaches, primarily through education to augment the family planning medical services.

The second is to develop model programs to address the needs of those who are already pregnant; to provide the opportunity for an improved pregnancy outcome, both for the baby and the mother, and in

the long term help keep these young mothers in school, and provide job training.

The third aspect is research into the causes and consequences of early teenage sexual relations, contraceptive use, pregnancy and childbearing and related issues.

The program is unique in that it approaches the problem in a comprehensive manner instead of concentrating on a single aspect such as medical services or education. It addresses all aspects of these problems simultaneously and develops comprehensive models for well-informed practice.

Senator WEICKER. Does this program provide family planning services to nonpregnant adolescents?

Mrs. MECKLENBURG. Yes; in this way. The legislation is very explicit. It provides counseling and referral for nonpregnant adolescents who need family planning services. But the money for family planning services cannot be used if these services are available elsewhere in the community.

We are trying to avoid duplication and encourage networking among existing agencies. This is very important because the teenager often has difficulty finding the many agencies providing the services that she requires.

It is very important to encourage the building of bridges among these existing service agencies.

ADOPTION COUNSELING

Senator WEICKER. I am not going to rehash and go around again on the squeal rule, that has been well covered. But I notice in your statement there is still considerable concern about the continuing trend of adolescent sexual activity at younger ages and the subsequent increase in teenage pregnancies. You go on about these model approaches which emphasize the participation of family members in dealing with these problems, and also encourage adoption as a viable alternative.

It seems to me that for an administration that is trying to get out of people's lives, you people get smack in the middle of it. In that sense I don't understand why we are out there. Maybe you can explain to me.

And I think adoption is a great thing, but why are we finding it necessary to promote adoption to pregnant teenagers? I don't understand that.

I am not saying one is better than the other. I just don't understand why we are promoting this.

Dr. BRANDT. The question is adoption versus other approaches. It is an alternative that a teenage mother may want to consider if for one reason or another she decides that she cannot keep the child.

We believe that this kind of information is helpful since we are dealing with what is a significant health problem in this country—namely, teenage sexual activity and teenage pregnancy.

Senator WEICKER. I see that you are giving information that this teenager should put the baby up for adoption. Is that it?

Dr. BRANDT. We are not trying to tell teenagers that they ought to put a baby up for adoption, but we are trying to give them the widest possible range of information to enable them to cope with their pregnancy.

Mrs. MECKLENBURG. Perhaps I can provide additional information.

Senator WEICKER. Would it be fair to say that you wish to minimize family planning services—in other words, before the fact—and coming on heavy after the fact. That is the general impression I get.

Dr. BRANDT. No; it is both, sir. Our programs include counseling, advising, and educating teenagers about what the consequences of sexual activity are, and how to deal with them. The projects refer teenagers to family planning services if they require them, help the teenager should she become pregnant, and help her through the continuum of the pregnancy.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. Well, obviously, we will have to go into depth in your testimony for the record to see where the emphasis is placed.

I have further questions to which I want responses for the record.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

Questions Submitted by the Subcommittee

PRIMARY CARE BLOCK GRANT

Question: In addition to placing the primary care block grant under your jurisdiction, I understand that legislation will be proposed to fund family planning, migrant health, and black lung activities under this block grant. If this block grant expansion is not approved, what will your request for the family planning, migrant health, black lung and community health programs be. Please provide exact amounts for each catagorical grant.

Answer: The following summarizes the impact on the Health Resources and Services Administration and on the Office of the Assistant Secretary for Health accounts of restoring the Primary Care categorical programs and the MCH Block Grant as they exist under current law to the Health Resources and Services Administration in 1984:

	1983 Continuing Resolution		1984 President's Budget		1984 Current Services	
	Pos.	Dollars	Pos.	Dollars	Pos.	Dollars
Bureau of Health Care Delivery and Assistance Direct Operations	739 1/	$38,351 1/	343	$20,091	707	$37,471
Program Management (Categorical Programs and MCH Block Grant)	217	$16,681	162	$10,782	217	$17,459
	(45)	($2,600)	(---)	(---)	(45)	($2,722)
Family Planning	---	---	--- 2/	--- 2/	66	$3,498
OASH Primary Care and MCH Block Grant Direct Operations	40	$2,060	40	$2,060	---	---

1/ Includes 66 positions and associated support dollars for Family Planning.
2/ In OASH proposed Primary Care Block Grant.

The 1984 current services level for BHCDA Direct Operations: excludes 66 positions and $3,498,000 required for the Family Planning activity which has been transferred to the Office of the Assistant Secretary for Health; includes positions and funds from the OASH Block Grant for total restoration of 370 positions associated with Primary Care categorical programs and MCH BLock Grant 15% set-aside provision and mandatory increases associated with the 370 positions; excludes 6 positions and $278,000 associated with reduced activity for NHSC Scholarship program.

The 1984 current services level for the Program Management activity: includes 55 positions and support dollars and mandatory increases for HRSA overall agency management of Primary Care categorical programs (35 positions and $2,117,000); of MCH Block Grant and 15 percent set-aside (10 positions and $605,000); and of Bureau of Health Professions and Health Planning activities, 35 other-than-permanent workyears, and other costs such as centralized payments (10 positions and $3,955,000).

In response to your specific question, our current legislative proposal for the primary care block grant would consolidate the three categorical programs you mention and would remove certain disincentives to State acceptance of this block. If this proposal is not enacted it would be necessary to restore funds and positions related to the three categorical programs proposed for inclusion in the block and for continued operation of the community health centers as a categorical program. Additional funds and positions would be required as follows:

Health Resources and Services Administration (HRSA)

	Pos.	Amount
Migrant Health	+36	+$ 1,719,000
Black Lung	+ 8	+ 382,000
Community Health Centers	+220	+$10,504,000
HRSA Program Management	+ 35	+ 2,117,000
	+299	+$14,722,000

The 220 position restoration for CHCs includes 20 positions currently in the OASH block grant request which would be restored to HRSA.

Grant funds also included in the OASH block grant request for 1984 would be appropriated to HRSA as follows:

Migrant Health	+$ 38,104,000
Black Lung	+ 3,120,000
Community Health Centers (under existing block grant legislation)	+ 295,000,000
	+$336,224,000

Additional funds and positions would also be required in the OASH appropriation for the family planning program as follows:

Office of Assistant Secretary for Health

	Pos.	Amount
Family Planning -	+66	+$3,498,000

Grant funds of $124,088,000 for family planning currently in the OASH block grant request would be appropriated in the Public Health Service Management appropriation.

POSITION REDUCTION

Question: In your statement you indicate that 844 positions -- primarily associated with the consolidation of programs into the block grants -- will be eliminated. For the record, provide details on the number of positions being eliminated from each program.

Answer: The total reduction of 844 positions includes 435 positions associated with block grants. Specifically:

- o 110 positions are directly associated with the proposed consolidation of Black Lung, Migrant Health, and Family Planning programs into the Primary Care Block Grant.

- o 200 positions are related to the conversion of the Community Health Centers categorical grant program to a block grant as authorized under current legislation. The proposed legislation removes disincentives to State acceptance of this block and requires implementation in Fiscal Year 1985.

- o 80 positions are related to the proposed elimination of the Maternal and Child Health 15 percent set-aside and continued implementation of this block grant.

- o 45 positions are related to management functions being eliminated as a result of conversion of these categorical programs to block grants and proposed changes in the Maternal and Child Health block grant.

The remaining 409 positions are distributed in the following programs:

- o 6 positions are eliminated because of the phase out of the National Health Service Corps Scholarship Program.

- o 72 are eliminated in the health professions program offset by an increase of 14 for debt collection for a net reduction of 58.

- o 130 are eliminated in the health planning program; and an additional 10 are eliminated from program management for reductions in the planning and health professions programs.

- o In addition, 150 positions supported by the Coast Guard and 55 positions supported by the Bureau of Prisons are also eliminated.

Question: What funds and positions will need to be restored in the event the block grants are not approved?

Answer: The 1984 request for block grants assumes enactment of legislative proposals for the Primary Care and Maternal and Child Health (MCH) block grants. The proposal for the primary care block

would consolidate funding for the migrant health, black lung, and family planning programs in an expanded block grant, and would remove disincentives to State acceptance of the existing block grant for community health centers. The proposal for the Maternal and Child Health block grant would eliminate the 15% set-aside for special programs. If these proposals are not enacted, funds and positions will be required for administration of the categorical programs that would continue and for activities funded under the MCH 15% set-aside. Additional positions and funds are also required to continue to provide technical assistance to MCH grantees. The required resources are as follows:

Health Resources and Services Administration (HRSA)

	Pos.	Amount
Maternal and Child Health -	+100	+$ 4,775,000
Migrant Health -	+ 36	+ 1,719,000
Black Lung -	+ 8	+ 382,000
Community Health Centers -	+220	+ 10,504,000
HRSA Program Management -	+ 45	+ 2,722,000
Total	+409	+$20,102,000

The restorations for MCH and CHCs each include 20 positions and funds which are requested in the OASH 1984 block grant. These 40 positions and $2,060,000 would be deleted from that request.

Grant funds also included in the OASH 1984 block grant request would be appropriated to HRSA as follows:

Migrant Health -	$ 38,104,000
Black Lung -	3,120,000
Community Health Centers (under current block grant legislation) -	295,000,000
Maternal and Child Health -	373,000,000
Total	$709,224,000

Office of the Assistant Secretary for Health

	Pos.	Amount
Family Planning -	+66	+$3,498,000

Grant funds of $124,088,000 for family planning in the OASH block grant request would be appropriated in the Public Health Service Management appropriation if proposed legislation is not approved.

HEALTH SERVICES RESEARCH

Question: Your budget for FY 1984 requests funding for four new research grants, yet the overall total of on-going or planned research in FY 1984 has been reduced by four. Please explain.

Answer: The total number of grants and contracts projected for FY 1983 is 58. This includes approximately 15 new research grants and 43 continuing projects. The total number projected in FY 1984 is 54. This includes approximately 4 new grants (a reduction of 11) and 50 continuing projects (an increase of 7). The increase in the 1984 continuation figure is a reflection of the 15 new starts in FY 1983. The total number of projects projected decreased by four between FY 1983 and FY 1984.

These projections assume optimum performance of all grantees with concomitant outyear funding at the originally approved levels. Newly implemented aggressive project monitoring will result in cost savings which may permit funding additional new starts within this budget request in FY 84.

Question: Are there enough health services researchers out in the field or do we need a training program?

Answer: There has been a marked decline in both the number and quality of investigator initiated proposals submitted by newly trained health services researchers. We see proposals by individuals with training in one of the academic disciplines associated with health services research but these are not often contextual to the multidisciplinary complexities of health services research.

We are presently assessing whether this reflects a need for Federal support of individuals in a health services research setting with the availability of appropriate academic disciplines, or whether it is primarily a function of the decline in availability of funds to support health services research.

Question: Isn't it true that by reducing the number of research grants available, you are sending a negative message to the young scientists which may result in a decrease of interest in doing research in this area?

Answer: There is little doubt that the reduction in the number of research grants that can be awarded by NCHSR has had an impact on the size and quality of the research community. The number of applicants for grants has declined in the past two years. Perhaps of more significance is the fact that many experienced investigators faced with the reduced probability of receiving support are now doing research in other areas of inquiry. Even if the funds available for health services were to be increased significantly, some of these researchers would not return to this field. New young investigators, therefore, face two problems. Not only are research funds in short supply making it difficult to further develop their skills, but senior colleagues who might guide and assist their research are less readily available as well.

COST CONTAINMENT RESEARCH

Question: With rising health care costs as important an issue as it is, what kind of research projects on cost containment are you currently supporting or planning to support?

Answer: Cost containment has been one of the priorities of the National Center for Health Services Research (NCHSR) for the past decade and the findings from this research program already have had a major impact on health policy. For example, NCHSR studies of case mix in hospitals resulted in the development of the DRG approach to reimbursement that is now being introduced as a cost containment strategy by the Health Care Financing Administration. Studies of the cost implications of health insurance programs provided the basis for the recent proposal to tax some portion of the health benefits that are being provided by employers - an approach that might well reduce the cost of care by limiting excessive first dollar coverage.

Studies now being supported examine the following issues: the factors that influence extended length of stay in hospitals; the characteristics of the hospital industry that influence excessive investment in construction and technology; the cost impact of alternative approaches to paying for nursing home care; the factors that determine the pattern of treatment and cost of critically ill patients in hospitals; and the strategies that might be employed to reduce the cost of laboratory tests by identifying those that contribute no significant new information for diagnosis or therapy.

In FY 1984, NCHSR will focus on three major issues in the area of cost containment: (1) The consequences of using co-payments and other approaches to rationing consumer use of services; (2) The cost and benefits of technology; and (3) The cost implications of modifying taxation and regulation policies in the health care industry.

In the area of cost sharing, NCHSR will seek proposals that examine such factors as:

- o the impact of increasing cost sharing on inpatient cost, prices, and quality of care;
- o the differential impact of increased cost sharing on the use of services such as preventive and primary care;
- o the impact of a more competitive public sector on the benefits and costs of private insurance.

In the area of technology assessment, NCHSR will explore such matters as:

- o the analysis of the costs and benefits of various procedures for evaluating cardiac status;
- o the analysis of patterns of use and benefits of diagnostic radiology;
- o the analysis of the cost and effectiveness of such surgical procedures as prostatectomies and caesarean sections.

In the area of taxation and regulation policy, NCHSR will seek proposals to study such matters as:

- o the relationship between tax subsidies and the matter of health insurance coverage;
- o the analysis of reimbursement pools of publicly funded programs;
- o the impact of State regulation of competition between insurers and the level of consumer coverage.

EVALUATION OF PROSPECTIVE PAYMENTS

Question: How are you planning to evaluate the new prospective payment approach recently passed by Congress?

Answer: The NCHSR is not planning a separate evaluation of the new prospective payment program recently passed by Congress. However, the Center's Hospital Cost and Utilization Project (HCUP) is designed to determine the reasons for differential patterns of admissions and treatment among hospitals and to assess the impacts of these differences on costs and outcomes. An important aspect of this research is the development and evaluation of alternative measures of hospital case mix including evaluation of Diagnostic Related Groups (DRG's) which are an important element in the prospective payment approach. HCUP currently incorporates several studies which consider various aspects of the prospective reimbursement experience in several states. Further, the Center through its extramural grants program will consider proposals from investigators seeking support for research to examine alternative prospective payment systems.

CURRENT COST SAVINGS PROPOSALS

Question: Your opening statement mentions research findings currently being used for tax proposals and changes in medicare payments. Can you please elaborate on these findings?

Answer: The National Center for Health Services Research estimates that the current revenue loss from exempting employer-paid health insurance benefits from taxation will amount to $20.4 billion in Federal income taxes in 1983, and another $10.3 billion in State and Social Security taxes. NCHSR has specifically estimated the effects of the Administration's proposal to limit the amount of premiums which are not taxed. By taxing premiums in excess of $2,100 for family coverage and $840 for individual coverage, the Federal government would realize an additional $2.3 billion in income tax revenues during the year and affect 16.5 million employees (or about a quarter of those with employer insurance).

More generally, with respect to the Administration's proposal for health incentive reforms, the NCHSR's National Health Care Expenditures Study (NHCES) has provided information, analyses, simulations, and other assistance to those responsible for developing the proposals aimed at employer-provided health insurance benefits. Specifically, NCHSR:

o Made widely available estimates of employment-related insurance premiums and enrollment, the size and distribution of the tax exclusion of employer-paid benefits, the number of employees and revenues affected by alternative ceilings on tax-free benefits, the availability of multiple options within employer groups, and existing cost-sharing provisions for hospital use and physician office visits. This information has been furnished to the public in general, and in particular to the Assistant Secretary for Health Planning and Evaluation, DHHS, the Council of Economic Advisors, the Treasury Department, and other Federal policymaking agencies.

o Provided specific estimates of hospital cost-sharing provisions and simulations of alternative policies related to the taxation of employer-paid premiums requested by the Council of Economic Advisors.

o Provided the Treasury Department with specific information on the number and type of tax-filing units where more than one employee was enrolled in an employer-supported plan.

o Consulted with the Office of Management and Budget on the availability of alternative health insurance benefits to unemployed workers with access to another family member's employment-related plan.

o Will continue to assist these and other policymaking agencies by providing unpublished estimates and simulations which they request, analyzing the determinants of health insurance benefits, estimating the effect of alternative policies on health expenditures, and developing further information about the alternative employer-provided benefits and coverage available to multi-worker families.

With regard to Medicare payments, and recognizing the financial implications of cost-based reimbursement, in 1969 the NCHSR funded John Thompson at the Yale University School of Medicine to develop a method of grouping patients according to their need for medical services. This basic health services research resulted in the creation of a scheme for categorizing hospital patients now known as diagnosis related grouping (DRG). The Administration is currently implementing a strategy of prospective reimbursement of hospitals for Medicare patients using the DRG technique.

Finally, the Center's Intramural Research program, through its Hospital Cost and Utilization Project (HCUP), is examining the implications for hospitals of such a prospective payment system based on DRGs in comparison with Disease Staging. Disease Staging is another method that can be used to classify patients into homogeneous groups for reimbursement. DRGs rely partially on resources use to classify patients, while Disease Staging is based only on medical criteria of severity of illness, excluding treatment decisions. The HCUP study is examining whether these two methods would provide different reimbursement incentives.

HEALTH CARE TECHNOLOGY RESPONSIBILITIES

Question: In FY 1982 the NCHSR assumed responsibility for the management of research projects for the National Center for

Health Care Technology. How do you plan to meet these responsibilities in the future?

Answer: Following its establishment under Public Law 95-623 (the Health Services Research, Health Statistics, and Health Care Technology Act of 1978), the National Center for Health Care Technology (NCHCT) worked in very close cooperation with the NCHSR. Technological developments are closely related to the delivery of effective and economical health care and consequently NCHCT, during its formative period, relied heavily on the considerable experience of NCHSR in identifying and evaluating medical technologies. One of the chartered peer review groups which reviewed grant proposals for NCHSR (the Health Care Technology Study Section) assumed the additional responsibilities of evaluating applications for the Technology Center; NCHSR's technical and administrative personnel worked very closely with the staff of NCHCT in designing and managing its research priorities and procedures. As a consequence, the demise of NCHCT did not cause major disruptions in administrative matters or in research direction when NCHSR assumed responsibility for the technology research program. Although considerably reduced in scope by competing demands for funds, technology assessment has again become an area of priority interest to NCHSR.

NCHSR STAFFING

Question: You are requesting five new positions in the FY 1984 budget -- specifically what will they be used for?

Answer: The five positions requested in the FY 1984 budget are for NCHSR's Office of Health Technology Assessment (OHTA).

At the request of the Health Care Financing Administration (HCFA) the Office of Health Technology Assessment carries out studies of the safety and effectiveness of medical devices and procedures. Based on the results of these technology assessments HCFA makes decisions concerning coverage of these devices or procedures by Medicare.

The funds for the five positions will be transferred to NCHSR from the Medicare Trust Funds. We believe this to be an appropriate use of the Trust Funds since these assessments will determine whether specific procedures are of sufficient safety and efficacy to be reimbursed by Medicare.

Question: To what extent is the size of the staff of the NCHSR adequate to carry out your various mandated responsibilities?

Answer: With the approval of the five positions requested in FY 1984, the size of the NCHSR staff is adequate to perform our mandated responsibilities.

Question: How much work is done on a contract or consulting basis?

Answer: The NCHSR has obligated $200,000 in FY 1983 funds for ADP support activities carried out by contract or consultants. These activities are limited to highly specialized computer programming support for our research data collection activities.

Approximately $40,000 has been obligated in FY 1983 funds for consultant expenditures involving technical review of proposed papers and manuscripts. Another $50,000 will be obligated to provide syntheses of research information and to support user workshops requested by State and local government participants in the User Liaison Program.

TRUST FUNDS TRANSFER

Question: I understand that you are proposing new appropriation language to transfer $300,000 from the Medicare Trust Funds to your account. Why are you proposing this and for what will the money be used?

Answer: At the request of Health Care Financing Administration (HCFA) the NCHSR's Office of Health Technology Assessment carries out studies of the safety and effectiveness of medical devices and procedures. Based on the results of these technology assessments HCFA makes decisions concerning coverage of these devices or procedures by Medicare. The $300,000 requested for transfer from the Medicare Trust Fund represents the costs associated with personnel carrying out the technology assessments. The budget request includes 5 new positions which will be supported with these funds.

USER LIAISON PROGRAM

Question: The FY 1983 Report of this Committee included Language which indicated the Committee's intention that the NCHSR continue, improve and strengthen working relationships with State and local government officials through its User Liaison Program.

Would you please provide the Committee with a brief description of the purposes of this program and the types of activities it undertakes?

Answer: The User Liaison Program is designed to address the information needs of State and local government officials who have major responsibility for policymaking that affects the planning, management, delivery and financing of health services.

NCHSR's commitment to strengthening working relationships with State and local governments through its User Liaison Program is based on two significant realities:

- First is the substantial and growing responsibility of State and local governments in recent years for organizing, delivering and financing health services. Since NCHSR's mission is to provide information that will contribute to improving the nation's health care delivery system, a program of liaison with those responsible for that system at the State and local level is most appropriate.

- Second, a national health services research capacity is essential if we are to examine many of the issues and problems common to a large number of State and local jurisdictions. This is particularly important given the lack of such expertise at the State and local level, the

likelihood that significant resources to conduct important analyses will not be available in State and local budgets, and the need to avoid a situation in which a number of State and local governments utilize their limitied resources conducting duplicative research on the same problems.

Resource limitations have reduced the capacity of the User Liaison Program to pursue aggressively its workshop relationships with State and local governments. However, by using the resources available through ongoing, funded projects as well as NCHSR staff, the Program has been able to develop and disseminate a modest amount of research relevant to the health care delivery problems of many State and local governments.

The NCHSR User Liaison Program undertakes three major types of activities:

- o The development of syntheses of research findings on problems identified as critical by State and local government officials in need of comprehensive, objective and critical analyses of an entire base of knowledge in a particular area, such as the design and financing of State programs for community-based long term care services, and State options for addressing catastrophic health expenses.

- o The conduct of workshops undertaken at the specific request of State and local legislative and executive officials, and planned and cosponsored in cooperation with such officials. These workshops deal with the topic of the research syntheses, as well as other problems of State and Local importance, and are designed to disseminate what is known about these problems and to assist such officials in applying existing knowledge to their particular jurisdictions.

- o Professional consultation in response to specific requests from State and local government officials on particular issues and problems of major concern, such as the potential effectiveness of hospital-based coordination, assessment and monitoring of elderly patients, and the use of forecasting to estimate the costs of state health programs.

Question: What has been the reaction of State and local government officials in terms of their interest and participation?

Answer: The reaction of State and local government officials who have participated in the program has been most supportive and encouraging. As a result, we have, within our limited resources, made efforts to expand the network of such officials who participate in these activities.

Question: Have requests for information and consultation increased?

Answer: The expansion efforts of the Program has led to an increase in the volume of requests for information and consultation. For example:

o The State of Connecticut has been most active in seeking the assistance of the NCHSR User Liaison Program on a variety of problems. For example:

--The Public Health Committee of the Connecticut House of Representatives has worked with the Program to examine the feasibility, costs, and potential effectiveness of initiating a State demonstration project for hospital-based coordination, assessment, and monitoring of elderly patients. The proposal has gained considerable support in the Connecticut Legislature, and we have been asked to provide consultation to the Public Health Committee in assessing the appropriateness of the evaluation plans developed for this demonstration project.

--Research and related information have also been provided to the Connecticut Office of Policy and Management and the Connecticut Commission on Hospitals and Health Care.

--Recently, the Executive Director of the Business Coalition on Health for the Greater Hartford area, contacted the Program and discussions are currently underway to plan for the cosponsoring of a seminar for the Board of Directors to provide research findings on various hospital cost issues.

o The State of Florida has also been active in stimulating a number of collaborative efforts with the Program. For example:

--A seminar for State legislators and their staffs was conducted last December on strategies for controlling hospital costs.

--At the request of the Florida Governor's Task Force on Competition and Consumer Choices in Health Care, several presentations were conducted on research relevant to hospital reimbursement systems, hospital competition, and consumer choice.

o At the request of the South Carolina Comptroller's Office, a seminar was recently conducted for various senior officials on the use of computer modeling and forecasting methods for projecting the costs of state health and human service programs.

o A number of executive and legislative officials from Alaska have participated in NCHSR User Liaison Program activities, and a workshop on rural health care delivery problems was conducted in December, 1981 in cooperation with the Alaska Department of Health and Social Services.

o Issues surrounding the provision of long-term care services to the elderly have been of primary concern to State and local governments, and several activities on this issue have been undertaken, including workshops on various aspects of this problem for officials from Maine, Connecticut, Vermont and Hawaii.

o The NCHSR User Liaison Program has also worked closely with the Department of Human Services and the Department of Health Environment in the State of New Mexico on issues ranging from health planning to maternal and child health.

Question: Does the User Liaison Program deal only with State and local governments?

Answer: The Program does not deal exclusively with State and local government officials. However, it has concentrated on such public officials for two reasons: first, their significant responsibilities for health care delivery; and second, because resource constraints in recent years have limited the capacity of the Program to expand beyond State and local governments.

Yet, NCHSR feels that there are other important health leaders to be reached, particularly the growing number of business coalitions. Our recent contacts with the Hartford, Connecticut Business Coalition on Health represent our first efforts to work with those types of organizations.

Question: What are some of the other issues that have been addressed by the activities of this program?

Answer: With respect to some of the other issues that have been addressed, health care cost containment has been prominent on the agenda of State and local government officials, and the Program has worked extensively in this area.

In addition, State and local officials have expressed considerable interest in health planning and the potential for health planning in the 1980s. Two workshops have been conducted on this subject for State and local officials from approximately 14 States.

Workshops and syntheses of research findings have also been undertaken on issues such as: the viability of rural hospitals; the performance of Health Maintenance Organizations; and the organization and delivery of health services to the medically indigent.

RESEARCH ON STATE AND LOCAL PROBLEMS

Question: This Committee's FY 1983 Report also directed the NCHSR to initiate, in FY 1983, at least two projects of directed contract research designed and monitored in close collaboration with State and local officials and focusing on State and local problems. How has this intent of Congress been implemented?

Answer: At the request of, and in collaboration with, the Joint Interim Committee on Health and Welfare of the Kentucky Legislature, we are currently in the process of designing a new research project which will examine the economic impact of generic drug substitution, as well as drug coverage and reimbursement rates, for Medicaid recipients in the State of Kentucky.

The Center recently sponsored two meetings with a number of senior State and local government officials in an effort to understand and describe, in a systematic fashion, the key problems

facing such officials now and in the future, as well as to assess the information needs related to those problems as they may be amenable to research and analysis.

The outcomes of those two meetings will provide NCHSR with priorities for future research strategies to address State and local health care delivery problems.

The problems identified range from health promotion strategies to the organization and financing of health services for long-term care populations.

NATIONAL CENTER FOR HEALTH STATISTICS

Question: You are requesting a 10% increase in your statistics program. Please explain the reasons for this increase and elaborate on any new projects you may be planning.

Answer: The Center maintains a number of different data systems, some of which are conducted annually and some of which are conducted at intervals of 2, 3, 5, or more years. Because of these intervals, the annual budget for NCHS will vary depending upon the number of surveys to be fielded during a given year as well as the funding required for planning and pretesting of these surveys. The FY 1984 request provides increases required to fund those periodic surveys that will be fielded or pretested during FY 1984 (National Ambulatory Medical Care Survey, National Mortality Survey, and the National Nursing Home Survey) as well as work with the Census Bureau on the redesign of the Center's population based surveys and payments to States for vital statistics data previously provided at no charge. Other factors resulting in an increase in the Center's budget include mandatory cost increases for other surveys and program support, additional costs of Census operations on the National Health Interview Survey, and maintenance of State vital statistics contracts. No new projects are planned for FY 1984.

The increases required by the factors noted above have been offset, to some extent, by decreases resulting from the phasing down of other periodic surveys (National Medical Care Utilization and Expenditure Survey, Hispanic Health and Nutrition Examination Survey, and the National Master Facility Inventory).

Question: To what extent has the National Center for Health Statistics been required to reduce the number of statistical collection projects it has funded in the past? How do you decide how often you will collect data and have you been required to collect certain kinds of data less frequently?

Answer: Recognizing the need to continue to provide baseline health data useful for trend analysis, yet cognizant of the very likely possibility of future resource constraints, the Center undertook a thorough review of its priorities and program plans. The results of that review are detailed in the report "Periodicity of Data Systems: A Data Collection Plan for Fiscal Year 1981-86." The periodicity study, while primarily emphasizing the technical feasibility or desirability of altering the frequency of data collection, sample size, and content of various surveys, also

explicitly addressed cost issues and the value and uses of various data systems.

In recent years, the Center has taken a number of steps to reduce costs while maintaining the viability of its major data systems. As outlined in the periodicity study, the frequency of the following surveys was reduced: the National Medical Care Utilization and Expenditure Survey, the National Health and Nutrition Examination Survey, the National Ambulatory Medical Care Survey, the National Master Facility Inventory, the National Nursing Home Survey, the Vital Statistics Followback Surveys, and the National Survey of Family Growth.

In addition to extending the periodicity of many of its surveys over the last few years, the Center has terminated funding of State statistical agencies under the Cooperative Health Statistics System, which previously supported Health Manpower, Health Facilities, and Hospital Utilization data systems in some States. There are currently 39 States funding their own statistical agencies.

Question: What kind of organizations rely on data collected by the National Center? What are some of the implications for these organizations if data were to be collected less frequently -- or not at all?

Answer: The National Center for Health Statistics is the Federal government's principal health statistics agency, and is primarily responsible for the collection, analysis, and dissemination of health statistics and information to meet a wide variety of user needs. Accordingly, the users of the Center's data are numerous, and encompass a range of agencies and organizations elsewhere in the Federal establishment, universities and researchers, private associations and enterprises. In addition to the distribution of publications and public use data tapes, the Center responds to well over 100,000 individual requests for data each year, and provides specialized advice and assistance on statistical matters to other Federal agencies and data users.

We believe that further reductions in the data collection frequency of these systems, or their elimination, would have a number of serious ramifications. Within the Public Health Service, for example, a number of agencies are engaged in collaborative activities with the Center that are important elements in meeting their own missions. Data systems currently offer an efficient and effective mechanism for meeting many of the data needs of these agencies for policy making and for understanding the changing nature of the health system. Many systems are designed to allow the inclusion of supplementary questions that address, in more specificity, the data requirements of various agencies. By reducing or eliminating systems, this capability would be diminished, resulting in either the reduced effectiveness of other agencies or increased costs associated with conducting alternative data systems. Similar problems can be expected with respect to other users of NCHS data. In many cases, NCHS data systems are the primary or only source of information for researchers and policy makers.

Question: The National Center is authorized to fill 503 positions. Are you at full complement? If not, why not? To what extent have there been delays in publications and dissemination of health statistics as a result of staff shortages?

Answer: At the present time the employment level is slightly below the authorized position level of 503. We are currently reviewing the staffing pattern and under the leadership of the new Center Director we are planning to change the staffing mix and increase our employment level to more appropriately reflect the personnel needs.

While the numbers of reports released on NCHS data have remained fairly constant, we are experiencing a lag in some types of reports and data released due to shortages of staff in various professional series. It is in the new emphasis areas such as health promotion activities, where the data has been delayed because of these shortage of analysts and other trained health professionals such as MD's, epidemiologists and statistical researchers. Our new recruitment efforts should partially alleviate this problem.

MODERNIZATION OF THE SYSTEM

Question: Are your data collecting and evaluating systems current with state-of-the-art technologies and are you capable of taking advantage of existing technologies? How much would it cost to modernize your systems?

Answer: We are reviewing our current efforts to apply state-of-the art technologies and are developing plans for what would be needed in the future to fully modernize our operations. We are reviewing data collection, data processing, the analysis process, the report preparation process, and very importantly, the whole question of the most efficient methods through which researchers and policy makers can access the available data.

This modernization program would address all aspects of our national health statistics system from data collection through data dissemination and all the steps in between. It would include not only analyses of hardware needs, but also software development, and new efficient methods for collecting, transmitting, analyzing, and accessing data. It is estimated that $12 to $15 million will be required over a three year period.

Question: To what extent does the National Center for Health Statistics utilize consultant or contract services to perform its research and data collection?

- o Please elaborate on the cost effectiveness of these services.
- o What percent of your budget is used for consultant services?
- o How are these consultants chosen and how do you evaluate the quality of their results?

Answer: The National Center for Health Statistics contracts with private agencies to assist in conducting certain aspects of its program. The major services purchased are primary

data collection through complex national sample surveys and some related processing, editing, and producing of publications. All contracts include strict quality control procedures established by the Center. The Center maintains the expertise and responsibility for systems design, survey content, analysis of data, and research into new methodologies. While the level of contract services varies according to the number of surveys fielded during a particular year, in fiscal year 1984 we estimate the cost to be about 15% of the budget.

To a limited extent, the services of consultants supplement the expertise of Center staff in areas such as nutrition and other health specialities and a small number of contract consultants provide specialized services in evaluating aspects of the data systems. These contracts are awarded competitively, and are monitored and evaluated by the Center's staff. Approximately 2% to 3% of the budget will be expended on consultant services in fiscal year 1984.

The use of contracts for data collection and of expert consultants in limited cases is felt to be a most cost effective alternative to hiring and training additional staff. Another important consideration is that the use of contracts and consultants afford the degree of flexibility necessary to field a variety of different surveys at varying intervals, many requiring different expertise.

Minority Population Surveys

Question: You are currently conducting a survey on the Hispanic population -- can you briefly elaborate on what you are surveying?

Answer: The Hispanic Health and Nutrition Examination Survey involves the interview and examination of approximately 16,000 Hispanics in three locations: the southwest United States, New York City, and Miami. The survey was begun in June 1982, and will be completed near the end of 1984. The examinations include complete medical history, physician's general medical examination, body measurement, dietary interview, laboratory tests on blood and urine, X-rays, spirometries, electrocardiogram, and other physiological measurements. Data collected in this survey will provide estimates on the prevalence of selected health conditions, indicators of health and nutritional status, and the measurements of the health status of Hispanics, which can be compared with similar measurements made in national surveys.

Question: Have you in the past, or will you in the future, do similar surveys on other minority populations?

Answer: NCHS is primarily oriented toward producing data on the national level, and has not, in the past, undertaken surveys of other minority groups. The survey of Hispanics has been undertaken in response to the Department's Hispanic initiative, as well as interest expressed by the Congress. While NCHS has no current plans to conduct similar surveys of minority populations, the systems maintained by NCHS are capable of responding to priority data needs on these populations should they arise.

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Question: Are your data systems capable of producing adequate information for analysis of the health problems of these minority populations?

Answer: In some cases yes, and in others, no. Most of our data systems are based on sample surveys since the costs of covering the entire population are prohibitive. From these surveys we are able to produce information on the black population because they constitute about 12% of the U.S. population. Other minority groups account for much smaller percentages of the population and we are not able in most cases to make reliable estimates.

We do feel, however, that knowledge of the health status and health need of these populations are important and there are mechanisms to provide us with some insights.

First, there is the vital statistics system which provides information on 100% of the births and deaths in this country and this includes demographic and limited medical data surrounding these events. Analysis of this data has traditionally been used to discern differences between racial and geographic groups.

Second, we can oversample special groups in some surveys to provide additional information on that group or we can conduct special surveys of target populations such as we are currently doing in the Hispanic Health and Nutrition Examination Survey.

Third, we share our methods and provide technical assistance to States and others so that they can do directed surveys in smaller geographic areas. To this end, 39 States have designated State Centers for Health Statistics which provide us with a focal point for such efforts.

SMOKING AND HEALTH

Question: It is obvious that smoking and its affect upon the health of the individuals is a priority item in the Office of the Assistant Secretary for Health. What progress has been made to encourage our citizens of all ages to quit and to discourage others from starting to smoke?

Answer: The Office on Smoking and Health strives to maintain an aggressive program by continuing its efforts to alert both the general public and health care professionals to the harmful effects of cigarette smoking. Significant progress has been made to reduce smoking and this is evidenced by the fact that per capita consumption is at it's lowest level since 1957. Our anti-smoking strategies fall into three areas: public information activities, technical assistance and information programs, and the Surgeon General's Report.

Public Information Activities - The current emphasis of our public information campaign is to encourage young people not to smoke. This is the most important area to target because 75% of all smokers begin before age 19. Successful television, radio and print materials have been developed and distributed with the help of local health agencies. This office works closely with health departments in the marketing of these materials. An evaluation of the media effort for the period of September 1982 through March 1983 indicated that the public service announcements were aired an average of 25

times per month. It is estimated that over $5 million worth of air time has been generated during this 6 month period.

Technical Assistance and Information Programs - The Technical Information Center which serves the national and world-wide community, responded to over 4,000 requests for scientific and technical information. It also services as the primary resource for researching and preparation of the Surgeon General's Report and continues to serve as a World Health Organization collaborating center for reference on smoking. Also, the smoking and health program provides technical assistance to local health departments and voluntary health organizations to institute individual smoking and health information programs. The response from the local agencies has been positive. The technical assistance provided by this office enabled successful anti-smoking information and education campaigns to be carried out.

Surgeon General's Report - Since 1967, the Department has been required to report annually to the Congress on the health effects of smoking. This annual report has become one of the most significant scientific and public health documents in the world. These reports contribute to public understanding of the hazards of cigarette smoking.

Question: Is the number of people who smoke still declining?

Answer: The last assessment of smoking prevalence was conducted in 1980. At that time the prevalence was continuing to decline. Funds are requested in FY 1984 to support a survey which would provide information to enable us to continue to monitor the changes.

INFORMATION/MEDIA INITIATIVE

Question: You are requesting an increase of $362,000 in your public information and media activities relating to smoking.

It is my understanding that DHHS pays to develop the media advertisement but allows the private organizations such as the Lung Association to distribute them. Why must the Department pay for the production?

Answer: There is ample evidence that the public responds to health information about smoking when it is sympathetically and effectively presented and when the accuracy of the information is unassailable.

Since 1979, the Office on Smoking and Health has developed public service announcements for radio and television which are in most cases distributed directly to radio and television stations with the Public Health Service as the sponsoring agency. Within the past year the Office has developed an initiative with community health agencies wherein Public Health Service television spots are made available to the local health agencies. For a very modest investment, the logo of the local agency is put on the spot, showing the local agency as the sponsor. The initiative satisfies a number of needs. Two of the primary needs are for local health departments to have access to quality smoking and health public service announcements and for greater actual exposure for the product

through increased air time. The first is satisfied by identifying the announcements with the local logo and the second by the fact that the stations prefer locally sponsored materials to those with national logos.

The Office has also worked with national voluntary health organizations in joint media efforts. For example an announcement which had been previously distributed by the Public Health Service, was re-released by one of national voluntaries. Thus, this announcement received a second exposure of air time for a very small investment. On two occasions, announcements addressing specific disease entities were jointly sponsored by the Office on Smoking and Health and the appropriate voluntary health agencies.

Question: If we stopped producing these advertisements, would the private sector take up the slack?

Answer: Historically, the Federal government and the voluntaries have been active in this area for over 25 years. The concerted emphasis placed on the nation's number one health issue has traditionally fluctuated in relationship to the emphasis the Federal government has placed on this problem. It is safe to assume that the voluntaries would remain active. It is uncertain whether this activity would expand or contract if there were a decrease in emphasis by the Federal government. Of even greater significance would be the clear signal to the public health community, the national voluntary health organizations and the general public that the Federal government was placing a reduced level of emphasis on the Nation's number one health problem.

CIGARETTE WARNING LABEL

Question: What is the administration's view on the effectiveness of the existing cigarette warning label?

Answer: Most Americans are generally aware that smoking is hazardous, however many consumers still do not know enough about the specific dangers they face in smoking. The Administration is very much concerned about educating smokers to the multiple specific health risks they face to permit fully informed decision making. The Department believes that alerting the public to these hazards is appropriate and necessary. For many years DHHS has supported a stronger health warning.

Question: Would the "Rotating Message" proposals have a greater impact?

Answer: There is a clear gap in the public knowledge about the specific dangers posed by cigarette smoking. A system such as this could present disease-specific information that would address this gap in the present knowledge.

CIGARETTE ADDITIVES

Question: How would it be helpful to know what additives the cigarette manufacturers add to their product to enhance flavor?

Answer: Access to the list of ingredients would permit assessment of potential additional health risks, over and above those intrinsic to the cigarette itself.

Question: How would such a requirement protect the smoker?

Answer: If additional risks are identified, smokers will be able to make more informed choices.

Question: If such information were required of the manufacturers on a "Trade Secret" basis, what steps would the Department take to keep this information confidential?

Answer: Information obtained on a "Trade Secret" basis would be treated in accordance with the Department's system for handling confidential information. The Department would exercise all reasonable care to protect this information.

HEALTH PROMOTION

Question: Health Promotion is one of the highest priorities in the PHS budget. This year you are requesting $3,015,000, an increase of 63 percent over last year. Please describe a few of your successful prevention activities and how they have affected the health of our citizens? Can you show how these activities have impacted on the rising cost of health care? How have these activities impacted upon the productivity of this country?

Answer: Progress in disease prevention should be measured in terms of the reductions of preventable health problems - the absence of illness, injuries, and deaths that, based on previous experience, might otherwise have been expected to occur. We have had some strikingly successful activities in recent years which have had a substantial impact on improving the health of Americans. Examples include: our childhood immunization initiative which has achieved immunization levels above 95% for American children; efforts to enhance prenatal health and behavior which have yielded infant mortality rate declines of about 4% per year over the last decade down to an all-time low; strengthened efforts at high blood pressure control which have achieved fully a dramatic improvement in the share of the hypertensive population whose high blood pressure is under control; a 25% reduction in smoking over the last 15 years, and a 10% to 15% reduction in consumption of total fat, saturated fat and cholesterol over that same period. The result of these latter gains in hypertension, smoking, and diet have collectively yielded a 40% reduction in stroke deaths and a 25% reduction in heart attack deaths over the decade from 1970 to 1980. Perhaps even more importantly, these changes have been substantial enough to affect the life expectancy of Americans. Between 1970 and 1980, the life expectancy of a 45 year-old American increased by 6.6 percent. Together, these represent important gains in our investment in human capital and the lives saved or enhanced as a result can be expected to contribute measurably to our national productivity.

Question: What activities are other agencies of the PHS involved in concerning disease prevention, health information and health promotion? Please include those activities supported by preventive health service block grants.

Answer: The following table indicates the level of health promotion activity in the Public Health Service:

Budget Resources (dollars in millions)	1983 C.R.	1984 President's Budget	Increase or Decrease
FDA			
Foods.....	$101.0	$106.1	+5.1
Drug & Devices.....	163.0	171.4	+8.4
Radiological Products..	27.9	28.8	+.9
National Center for Toxicological Research	20.3	21.2	+.9
Contingency Fund..... 1/	5.0	---	-5.0
Subtotal.....	317.2	327.5	+10.3
IHS			
Preventive Health.....	52.8	27.7	-25.1
CDC			
Venereal Diseases.....	47.7	48.5	+.8
Immunization.....	39.3	41.9	+2.6
Infectious Diseases....	34.9	34.4	-.5
Chronic/Environ. Hlth..	24.7	24.3	-.4
Occupational Safety....	57.5	54.6	-2.9
Epidemic Services.....	40.5	46.0	+5.5
Subtotal.....	244.6	249.7	+5.1
OASH			
Smoking and Health....	2.1	3.5	+1.4
Health Promotion.....	1.9	3.0	+1.1
National Youth Sports.	5.8	5.8	---
Physical Fitness.....	1.1	1.1	---
Adolescent Family Life	13.4	16.3	+2.9
Subtotal.....	24.3	29.7	+5.4
Preventive Health Block Grant.....	86.3	86.3	---
TOTAL, Direct Prevention	725.2	720.9	-4.3

1/ FDA is requesting a supplemental in FY 1983 to be used as an emergency fund for costs associated with incidents such as the infant formula and canned salmon recalls and the Tylenol product-tampering emergency.

Question: How are all these activities coordinated to avoid duplication and overlap?

Answer: The Office of Disease Prevention and Health Promotion in its leadership role provides the coordinative focus for policy and program activities in prevention. Through the monitoring of the implementation of the 1990 objectives and preparation of such documents as "Prevention '82", the Office seeks the effective use of resources for health promotion and disease prevention. This office for example, assigned lead agency responsibility for each of the objectives, and developed a tracking system for the implementation plans which have been developed.

COOPERATIVE AGREEMENTS

Question: Please explain the purposes of "cooperative agreements".

Answer: The purpose of a cooperative agreement is to assist a non-Federal agency with a project of mutual interest to the government and the agency. The funding is a form of assistance with substantial programmatic involvement by the government. The cooperative agreement approach was most appropriate for the National Health Promotion Training Network because it allows close cooperation and technical assistance.

The cooperative agreement mechanism in health promotion offers several important capabilities. First, for a relatively small investment we are able to foster an interest in health promotion in organizations with a vast network of local chapters and hence to increase the level of activity in health promotion. For example, our current cooperative agreements with the Red Cross, the YMCA, the Urban League and the Coalition of Hispanic Organizations allows us access to 3,000 chapters and more than 13 million people. Secondly, participation in the cooperative agreements insures that these organizations will be developing programs which are consistent with the scientific consensus supporting health promotion. Moreover, when program activities are developed, they are developed to reinforce the work of the other organizations and participants.

Question: Why are you requesting an increase of $425,000 for this activity?

Answer: The cooperative agreement approach has proven to be an effective means of stimulating health promotion activities nation wide, at a very low cost. We are therefore requesting a $425,000 increase in Fiscal Year 1984 to fund a total of nine cooperative agreements to expand the networks of groups which serve populations who are not now included such as worksites and schools. The specific organizations have not been identified at this time but the organizations will be national voluntary or professional groups with chapters or affiliates serving audiences such as women and youth, and sites such as businesses and schools.

SCIENTIFIC SUPPORT & TECHNICAL ASSISTANCE

Question: You are requesting an increase of $248,000 to increase scientific support and technical assistance. Please elaborate on to whom this support and assistance is provided?

Answer: The increase of $248,000 will allow the program to continue developing stronger prevention monitoring capabilities as well as increasing scientific support and technical assistance. This assistance will be provided to communities which have programs that emphasize reduction of health risks to the individual through changes in their lifestyle habits. The prevention monitoring will focus on the progress being made by the health agencies in implementing the 15 measurable health objectives to accomplish the Healthy People Goals for 1990.

Maintenance and encouragement of scientific support for prevention efforts is accomplished in a number of ways. Advisory

recommendations are made to the Assistant Secretary for Health regarding the allocation of research dollars for prevention efforts. The program staff encourage voluntary and professional organizations to support prevention efforts that have a sound scientific base. Technical assistance is offered to other Federal agencies as well as non-Federal groups. Dissemination of sound scientific information is done through the National Health Information Clearinghouse as well as through seminars, conferences and workshops.

TECHNICAL CONSENSUS MEETINGS

Question: Please explain what is meant by technical consensus meetings and how and why this project is useful.

Answer: Technical consensus meetings in prevention are a series of workshops modeled after the NIH Consensus Development Program Conferences which are aimed at reaching a consensus on current problematic issues related to prevention. This project is useful because it provides the professional and the general public with the most accurate current information about the benefits and risks of complex, sometimes controversial, prevention issues.

One of the major issues confronting the clinical community in the country today is: what range of preventive services ought to be offered to the well population by physicians? We are currently working with several of the major professional organizations, such as the American Medical Association and the American College of Physicians, to develop a set of recommendations which can be offered to practicing physicians on those preventive services that are reasonable to offer their patients at various age groups. Another example can be found in the area of health risk assessment, where quantifying health risks is an important issue in environmental and occupational health. We plan to hold a consensus effort on certain dimensions of the methodology involved in health risk assessment.

Other issues relate to the role of prevention medical education, the sorts of dietary guidelines which ought to be offered to Americans, the appropriate exercise regimens for cardiovascular fitness, the development of standards for community fitness and nutrition facilities. The results of these technical consensus exercises are disseminated widely in the form of a technical report series issued by the office.

ADOLESCENT FAMILY LIFE

Question: At the present time we can identify four other Federal programs that fund various services relating to the prevention of adolescent pregnancy and assistance to adolescent parents:

- o Family Planning Program
- o Title XIX of Social Security Act
- o Maternal and Child Health Block Grants
- o Title XX Social Security Act

Describe for us how the Adolescent Family Life program differs from these other Federal programs and tell us what you are doing to assure that you are not duplicating services.

Answer: The Adolescent Family Life program differs from all the others in two significant aspects. First, it is not designed as a services delivery program. All Adolescent Family Life care and prevention projects are demonstration models that can focus on developing the most innovative and cost-effective means of addressing the needs of adolescents and then providing this information to States and communities that require guidance with their own services delivery programs. Second, the other programs are designed to serve a broad range of age groups and do not have the adolescent as their sole focus, while the Adolescent Family Life program uniquely focuses on all aspects of the problem of premarital adolescent sexuality, pregnancy and parenting. The other programs, though providing services to adolescents, do not take these problems as their prime concern and consequently are not able to comprehensively address all dimensions of these problems simultaneously as does the Adolescent Family Life program.

The program has developed several formal as well as informal ongoing relationships with other Federal agencies, States and community groups to ensure that there will be no duplication of services offered.

Question: In this same area of concern, there are at least three other Federal programs that fund research in the areas of causes and consequences of adolescent child bearing and in services to prevent or alleviate these problems.

Please tell us how the research supported by the adolescent family life program differs from these other research programs?

Answer: Last year, before soliciting research proposals, we consulted other research programs to avoid duplicating their efforts. Research proposals were solicited from a broad spectrum of the research community and more than 140 proposals were received. Those proposals were reviewed for originality and feasibility by panels of non-Government research experts. Many proposals were scientifically meritorious and contained innovative ideas for studying the problems. Most other research contributes to basic scientific knowledge. The research activities of this program contribute to policy and program concerns. These two requirements utilize significantly different approaches to the subject matter.

Question: How are you coordinating the research in this area to avoid duplication?

Answer: Several existing processes within the Public Health Service assure that wasteful duplication will be prevented. For example, an interagency coordinating committee under the direction of the Office of Adolescent Pregnancy Programs (OAPP) exists to coordinate the research efforts of Title XX with those of other Federal agencies. In addition to such formal coordinating mechanisms, there has been an ongoing exchange of information and ideas between researchers at OAPP and other relevant agencies toward the end of avoiding duplication of effort as research plans and projects go forward.

Question: How do you plan to evaluate and disseminate all the information gathered from the research and demonstration projects?

Answer: Legislation requires that each demonstration service project must spend not less than 1 percent and not more than 5 percent of the amount received for the conduct of evaluations of the services supported under this title. All 50 grantees are establishing working relationships with colleges or universities in their states for the monitoring and evaluation of services. In addition, there will be central coordination of these individual evaluation efforts into a cross-cutting evaluation design which measures and compares the relative effectiveness and efficiencies of the various service models being tested in the 50 demonstrations. Our goal is to carry out the most effective dissemination strategy at the lowest possible direct cost to the Government. Plans are to use the many public media resources available to us often without charge. For example, we will use such communication channels as professional journals, popular magazines, publications in related children and youth fields, radio and television interviews, public forums and meetings, community newsletters and publications of state and local organizations with special interests in adolescent pregnancy. Program funds will be used only to facilitate this strategy or to supplement these channels if they prove inadequate to the task.

SERVICES PROVIDED BY GRANTEES

It is my understanding that the Adolescent Family Life program will not provide family planning to non-pregnant adolescents.

Question: Must they become pregnant before they are eligible for family planning services?

Answer: Legislation prohibits Adolescent Family Life grantees from providing family planning counseling or services unless these services are not available through other community programs.

Question: Would teenagers who have been pregnant at least once be eligible for prevention counseling services to discourage sexual relations?

Answer: Under Title XX any non-pregnant adolescent is eligible for prevention counseling services.

Question: If a non-pregnant teenager (or her parent) requested family planning counseling, how would the program respond?

Answer: If these services were not available in the community the program grantee may provide family planning counseling and/or referral services.

Question: In those projects offering both care and prevention services, how have the grantees screened those adolescents who are not eligible for family planning services?

Answer: There is no screening necessary to determine eligibility for family planning services. The only determination by the grantee is if these services are already available through other community programs.

Question: How do you justify this practice? Isn't it a bit like sticking your head in the sand?

Answer: To provide these services when they are already available from other sources would only divert funds from the primary mission of these programs which is to discourage premarital sexual relations and serve pregnant adolescents.

Question: Has this practice eroded the credibility of your programs among adolescents? How have you arrived at your conclusions?

Answer: Adolescent Family Life projects are still very new, most have been in operation for less than one year. However, the grantees have not indicated to us that they have experienced any erosion in credibility because they do not offer family planning services.

Question: If a pregnant teenager -- or her parent -- request referral for abortion counseling, how would the program respond?

Answer: Title XX prohibits grantees from providing abortion counseling and prohibits referral for such counseling except when an adolescent and her parents or guardians make such a request. In this instance the project refers the adolescent and her family to an agency in the community which includes abortion counseling within its range of services.

Question: In last year's testimony you repeatedly underscored the fact that the adolescent family life program was "principally a demonstration program" and the results of these demonstration projects would be "shared." What portion of your FY 1984 budget is earmarked for evaluation of the information received from the demonstration projects and what portion of the dissemination of this information?

Answer: Legislation requires each demonstration service project must spend not less than 1 percent and not more than 5 percent of the amount received for the conduct of evaluation of the services supported under this title.

No specific amount is reserved for dissemination. Our plans are to use public media resources which are often available at no charge. Program funds will be used to supplement when necessary.

Question: In last year's testimony you described sponsored forums as a means of dissemination of information. Have you evaluated this method over the past year? Have you developed additional methods of information dissemination?

Answer: During the past year the staff met with representatives of 60 private organizations and foundations to focus on improving services for pregnant adolescents, adolescent parents, their children, and families. The purpose of these meetings was to share information. The response of the participants indicated that this mechanism was very useful and we plan to continue this approach. Other dissemination methods will focus on the use of public media resources to distribute information.

DESCRIPTION OF PROJECTS

Question: Please describe all of the research and demonstration projects that have been funded. Please include the stated goals of the projects and the expected results. Have you received any preliminary results or reports? If not, can you request some?

Answer: The Adolescent Family Life program is designed to provide models for communities around the country to demonstrate effective care services for pregnant adolescents and adolescent parents and prevention services to reach young people before they become sexually active. Located in 38 States, the projects include 50 demonstration programs in which the Federal government provided initial funding to help eligible public and private non-profit agencies develop and evaluate services either directly or through linkages with other appropriate agencies. The community provided matching funds amounting to at least 30 percent of the cost of the project. The demonstration projects stress family involvement to help prevent teenage pregnancy and deal with the strains of adolescent parenting; care services for pregnant adolescents and adolescent parents; and prevention services relating to problems associated with adolescent sexual relations.

In FY 1982, 12 research grants were funded which are exploring such issues as, the influences of family, religion, school and peers on adolescent sexual behavior; the role of parental involvement and communication in childrens sexual values and actions; contraceptive use and clinic continuation among adolescents; factors affecting the provision of services to pregnant and parenting youth; and relevance of services in reducing welfare dependancy of adolescent parents.

No research or evaluation information is available at this time since the projects were only funded last fall. Reports from the first of the research projects will be available at the end of this year. Evaluation data from the demonstration projects will be available in the summer of 1984.

Question: What factors do you consider in evaluating research and demonstration applications for program funds?

Answer: The factors considered in evaluating research applications include:

-- the significance and originality from a scientific or technical standpoint of the goals of the proposed research;

-- the adequacy of the methodology proposed to carry out the research;

-- the qualifications and experience of the principal investigator and proposed staff;

-- the reasonable availability of resources necessary to the research;

-- the reasonableness of the proposed budget and duration in relation to the proposed research.

- The factors used in evaluating demonstration applications include:

  -- Whether the applicant organization is capable of carrying out the proposed project, including provision of adequate resources and facilities; qualifications of proposed staff are adequate to carry out proposed work plan.

  -- The applicant's presentation of the projects objectives, methods for achieving them, and results or benefits expected demonstrate a clear understanding of the purpose of the demonstration program.

  -- The applicant's project narrative describes a work plan which is comprehensive, clear, innovative, of high quality, feasible, has the potential for attaining the project's objectives, and appears worthy of replication.

  -- The applicant's budget contains estimated costs to the Government which are reasonable considering the anticipated benefits.

  -- The applicant's evaluation plan indicates an understanding of program assessment methods and reflects a practical, technically sound approach toward applying the evaluation methods proposed.

  -- The applicant's project expresses the priorities established by Title XX of the Public Health Service Act (Sec. 2005), such as: (a) projects serving areas with high need for services, (b) projects utilizing existing available programs and alternative funding sources, (c) projects demonstrating community commitment and involvement and (d) projects demonstrating innovative and effective approaches.

Question: Please define for us the term "prevention" as it is used in the Adolescent Family Life Program.

Answer: The program working definition of "prevention" was taken directly from the Title XX legislation which specifically lists "necessary services to prevent adolescent sexual relations...". Some example of the services listed are; pregnancy testing and maternity counseling, screening for venereal disease, and appropriate educational and vocational services.

Question: Can you give us examples of prevention activities used by the agencies that receive grants under this program?

Answer: A number of prevention approaches are being demonstrated.

- The Mount Vernon New York Public School project is an example of a classroom based model. In this pilot project for fifth and seventh grade students and their parents, a curriculum is presented to influence adolescents before they become sexually active. This effort is aimed at

promoting self-discipline, self-esteem, and personal responsibility.

- o In Nampa, Idaho the community health clinic project is an example of a community parent-child education program. They are conducting a two year parent training program aimed at supporting the role of parents as the primary sex educators of their children.

- o The Minnesota Institute in Anoka, Minnesota is an example of a media educational approach. This project provides prevention services in rural areas of the state using a series of video programs broadcast on local cable and public broadcasting stations.

Question: Can you provide us with any evidence that supports these activities or approaches are -- or will be effective?

Answer: One of the purposes of the adolescent family life program is to test the effectiveness of a variety of prevention approaches which might be used by state and local agencies. Individual program evaluations are being conducted for each prevention project. Initial results will be available in the summer of 1984.

Question: In your narrative you used the term "family centered approaches." Can you describe what is meant by this term?

Answer: A "family-centered" approach in the program means that parents and other appropriate family members are encouraged to participate in helping their children deal with their sexuality in a responsible way. In a society where there is a rising rate of premarital adolescent sexual activity, venereal disease, and early unintended pregnancy, parents have a stake in the consequences of the choices their children make and the way services are provided to them. The Administration believes that through stressing the importance of the family that premarital sexual relations can be reduced, and for those adolescents who are already pregnant, the family will be a support system which will enable the pregnant adolescent to deal with her pregnancy and complete her education.

Question: How do you intend to deal with the problem of the adolescent that is estranged from her family? How will you deal with the runaway?

Answer: The Adolescent Family Life legislation promotes constructive family involvement as an important part of the approach to solving the problems of teenage sexuality, pregnancy, and parenting. Every effort would be made by program services staff during the preliminary stage of contact to not only advise such adolescents about parental notification and consent procedures in the case of unemancipated minors, but to discuss the barriers existing between adolescent and parents with the hope of effecting a sufficient reconciliation so that services can proceed. Even with emancipated runaways or estranged minors the programs would make sustained efforts to assist the adolescent to reach out and obtain family support and guidance.

TRANSFER OF FAMILY PLANNING PROGRAM

Question: In fiscal year 1983 the family planning program was administratively transferred from the Health Resources and Services Administration to the Office of Population Affairs in the Office of the Assistant Secretary for Health. Please explain the rationale for this change.

Answer: The transfer of the family planning program consolidates those programs in the Public Health Service that are related to adolescent family life, family planning and population affairs. The administration gives a high priority to these vital health programs and is highlighting them by organizationally locating them in OASH rather than in one of the PHS agencies. Centralization of these related programs will provide consistency in management and policy making as well as eliminate the possibility of overlapping functions.

The consolidation of these closely related programs will have a positive effect on each. It eliminates the previous separation between the setting of overall policy in family planning and the operations which implement the policy. It also leads to greater management efficiencies by bringing the two operating programs -- Family Planning and Adolescent Family Life -- under a single program manager. For example, one grants management officer will serve grantees of both programs, and one unit will develop policy for all areas.

Question: It is my understanding that in fiscal year 1984, you propose transferring this categorical program into the primary care block grant. Since the block grant offers more discretion to the States on the use of health care funds, what priority do you believe would be given to family planning services?

Answer: Under the block grant concept, each State would be responsible for determining the priority to be given to specific activities funded by the grant. We are confident that the States will continue to give appropriate emphasis to this responsibility.

Question: If the transfer of the Family Planning Program to the primary care block grant does not occur, is it your intent that administration of the Family Planning Program remain under the Office of Population Affairs, or would the program return to HRSA?

Answer: If the family planning program is not included in the block grant, the categorical program would continue to be administered under the Office of Population Affairs.

Question: What would be the impact on Title X Family Planning Services if they were consolidated under the primary care or maternal and child health services block grants?

Answer: I believe that one must look at family planning as a part of primary health care. As an example, when a young women is sexually active it is important that she be immunized against German measles because of the known risk to a developing fetus. At the present time when she goes to a family planning clinic she can

receive contraceptive devices or drugs but must go somewhere else to get a simple immunization. In a primary care setting, screening for various kinds of illnesses would be a part of the total effort. In my judgment, the health of American women would be greatly improved with an integrated program.

Question: Have you evaluated the Family Planning services in each state? If so, are there any states that have not taken full advantage of the family services funds to establish a credible family services program? Do you have any sense of public concern about the family services programs in those States that have not been full participants in family planning services?

Answer: The role of States in the administration of Title X family planning funds and of other family planning services funds has been reviewed. In 33 of the 57 States and territories, State or territorial agencies are the sole Title X grantees. In 10 more States, which have more than one Title X grantee, a State agency is one of the Title X grantees. Finally, in 7 additional States, while not Title X grantees, State agencies have had substantial experience in administering family planning services funded through Federal programs other than Title X or through State resources. We believe that all States realize the value of family planning services and would be interested in administration of family planning services as part of a block grant.

Question: Describe the formula the Office for Family Planning used to allocate Title X funds to HHS regional offices. Do you plan to request a statutory change in this formula? If so, why and when?

Answer: The Office of Family Planning allocated Title X funds to the HHS regional offices according to an allocation formula based on such factors as: priority population at risk; percentage of women at or below 150 percent of poverty served; and the efficiency with which services are provided, e.g. the cost per Title X user. Since the formula is administratively determined, a statutory change is not needed. Each region will receive the same percentage of the total funds available as was allocated in FY 1982.

Question: What effect has the elimination of the family planning research funding authority by the Omnibus Budget Reconciliation Act of 1981 (P.L. 97-35) had on such research?

Answer: Only part of section 1004 of the Title X statute pertaining to research was repealed by the Omnibus Reconciliation Act of 1981. The deleted part pertained to actual authorization figures and a prohibition on the use of funds appropriated elsewhere to conduct or support research described in Section 1004. The retained language, plus language from the House Appropriations Report on the FY 1983 Continuing Resolution to the effect that Title X funds are to be used to "conduct services related research" has made it possible to continue the described research activities.

Question: Department officials have been quoted as saying that the so-called "squeal rule" will have little effect on the utilization of family planning services. On what basis is this statement made?

Answer: We have carefully considered the assorted arguments raised regarding the effects on minors of the parental notification requirements. We are not convinced that these effects can reasonably be predicted at this time. We also do not believe that sufficient data have been developed to support the contention of some commenters that an assurance of confidentiality is one of the major factors, if not the major factor, in the decisions of most minors to seek family planning services. In light of the various predictions concerning the consequences of this rule, we intend to monitor closely the effects of its implementation in light of any reliable data that are developed regarding its effects.

Question: At a meeting with staff, statistical evidence was quoted supporting this point of view. Please provide us with the source of these statistics.

Answer: A study by the Guttmacher Institute of unmarried female teenagers served by family planning clinics claimed that 54 percent thought their parents knew of their visit to the clinic and another 5 percent were not sure. The study claimed that if parental notification were required, 77 percent of the total would continue to use the clinic and 23 percent would not. This latter class was comprised of 15 percent who would continue sexual activity but use a nonprescription contraceptive method, 2 percent who would abstain, and 2 percent undecided. Four percent of the teenagers would continue sexual activity without using a contraceptive method.

UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES

Question: You indicated in your budget narrative that you will not support any additional students at the Uniformed Services University of the Health Sciences. You plan to phase out participation by 1989.

Why did you decide to send students to this program rather than to other medical and health science schools?

Answer: The USUHS curriculum is designed to prepare students for careers as uniformed services medical officers who are often called on to practice medicine under difficult physical and psychological conditions and to lead and manage large medical units and organizations. USUHS prepares students for these roles through medical training, leadership and management training, and by stressing the ideals of the military and medical professions. We in PHS are primarily interested in the development of medical officers who would be prepared to assume senior managerial positions in the PHS commissioned corps.

Question: I understand that this particular institution provides your students with specific training necessary for Public Health Service Officers. Why are you terminating the program? If the required service obligation is seven years, aren't your setting yourselves up for cyclic shortages by not sending students on a continuous basis?

Answer: Because of the anticipated physician surplus in 1990, we believe that PHS will be able to attract the quantity and quality of medical officers required. With regard to the cyclical

problem, although the commitment is seven years, the total time invested by the student if a three year residency is completed would be fifteen years. With this amount of time in service it is very unlikely that USUHS graduates would leave PHS until retirement age. In any event, medical officers trained at USUHS would represent a small percentage of total corps strength and we anticipate no shortages.

Question: Does the PHS have enough active duty PHS officers to meet a National emergency?

Answer: PHS commissioned corps strength is adequate to meet any public health emergencies comparable to those experienced in recent years such as Mt. Saint Helens, Three Mile Island, the mass immigrations, and legionnaires disease.

NATIONAL YOUTH SPORTS

Question: Please explain the reasons behind the transfer of the National Youth Sports program to OASH?

Answer: The National Youth Sports Program (NYSP) was created in 1969 and administered by the President's Council on Physical Fitness and Sports. Since that time, the program has been administered by the Office of Economic Opportunity and the Office of Community Services (formerly the Community Services Administration). The transfer of this program to OASH is in conjunction with HHS proposals to combine the community services block grant (which provides funding for NYSP) with the social services block grant. Because of the emphasis on health promotion and physical fitness programs within the Office of the Assistant Secretary for Health, the Administration considers this organizational unit the most appropriate to insure continued effective administration of the National Youth Sports program.

Question: What are your plans for this program?

Answer: We plan to continue the program in 1984 at the current level. The resource levels requested in 1984 will permit the program to continue to serve approximately 50,000 economically disadvantaged youth.

PHYSICAL FITNESS AND SPORTS PROGRAM

Question: How does the physical fitness and sports program relate to the Department's health promotion activities? Is there any duplication or overlap in these programs? If prevention is a priority, why haven't you requested an increase in physical fitness programs?

Answer: There is no duplication or overlapping of the programs of the President's Council on Physical Fitness and Sports (PCPFS) and the health promotion activities of the DHHS. The PCPFS was created by Executive Order of the President and directed to carry out a ten-point national program of physical fitness and sports. The Council's Federal responsibilities are in the area of amateur sports, physical education, physical fitness/exercise and sports medicine.

The efforts of the President's Council on Physical Fitness and Sports have contributed to a revolutionary change in the American way of life particularly in the public's awareness level of the relationship of physical exercise and good health and also in the numbers of people who actually exercise. Because of this awareness level, we feel there is no need to expand the program at this time. Our efforts will focus on maintaining the current activities of the Council and staff in promoting physical fitness for all and maintaining the increased level of public awareness.

Question: Is the Physical Fitness and Sports program involved in any way with planning for the 1984 Olympics? If so, may we have the details including any department monies involved?

Answer: The PCPFS serves on the Executive Board of the U.S. Olympic Committee (USOC) and attends approximately three USOC meetings per year. The Executive Director, PCPFS, is a member of the governmental liaison committee for the Los Angeles Olympic Organizing Committee for the 1984 Summer Olympic Games.

In those capacities the PCPFS has input into the planning for the 1984 Olympics. However, there are no Department monies involved other than time and travel costs for the aforementioned coordination services.

Question: Does the physical fitness and sports program get involved in the field in sports medicine? If so, what programs has the department supported over the past two fiscal years?

Answer: The Council sponsored The White House Symposium on Sports Medicine and Physical Fitness in November 1981 and will conduct another White House Symposium in November 1983.

Seminars dealing with various topics in the field of sports medicine have been co-sponsored and planned cooperatively with organizations such as the Universities of California, Arizona and Wisconsin; New Jersey Governor's Council on Physical Fitness; and American Medical Association; the American College of Sports Medicine; the American Orthopedic Society for Sports Medicine; and the U.S. Olympic Committee Sports Medicine Council.

The Council has taken the lead in hosting meetings to develop an ongoing liaison relative to conferences and information clearinghouses. In addition, the Council encourages research among the major sports medicine/exercise science organizations in the U.S.

PCPFS duties were recently expanded to include sports medicine services. As a result, a staff position in sports medicine/exercise science was established and that person is providing technical assistance to professional associations and public and private agencies.

The Council publishes for distribution through the Superintendent of Documents the "Physical Fitness/Sports Medicine, an Index of Published Articles" and distributes cooperatively publications such as "Sports Injuries in Children".

RETIREMENT PAY AND MEDICAL BENEFITS

Question: Your appropriation language proposes to change the Retirement Pay and Medical Benefits account from an indefinite to a definite appropriation and this gives you the authority to obligate against the next fiscal years appropriation.

Did the Department initiate this proposal, or was it the result of OMB discussion? What will this change accomplish? Is there a compelling reason for this change in language? Will this change, if accepted, impose any restrictions on your operation?

What will be the effect if we do not make the change in the appropriation language?

Answer: The proposal to convert this account from an indefinite to a definite appropriation is consistent with the Administration's efforts over the past two years to reduce the number of indefinite appropriations throughout the Federal government. The change would not restrict the operations of the program because a mechanism has been built into the appropriation language to guarantee that sufficient funds are available should the actual requirements exceed our appropriation request plus estimated reimbursements. The authority to obligate against subsequent appropriations has been requested to cover any shortages resulting from unanticipated costs in retirement payments, survivors' benefits, and/or medical care. The provision of these payments is mandatory. If no changes are made in the appropriation language, the program will continue to operate as it has in the past.

PHS MANAGEMENT

Question: How do you plan to increase the opportunity for small and minority firms to participate in the PHS contract and grant process? Describe your past efforts in this area.

Answer: Our efforts to increase the opportunity for small and minority firms in the PHS contract and grants process include maintaining and improving strong support for such firms in the contracting area and providing assistance to such firms to participate in those grant programs for which they are eligible. Although total PHS contracting dollars have declined from $966 million in FY 1978 to $676 million in 1982, the PHS dollars awarded to small businesses have increased during the same period from $138 million to $178 million, an increase of 29 percent. During the same period, our minority business support increased 100 percent, from $16 million to $32 million. These accomplishments have been the result of establishing challenging and reasonable goals for each PHS component based on the nature of the component's procurement mix and the contracting opportunities that are available for small and minority firms and monitoring goal performance through high priority reporting systems. As a management initiative, small and minority business achievement is monitored quarterly and measures are taken to remedy problems that hinder goal achievement.

The President has issued a special initiative to increase minority business participation by 10 percent over the 1982 performance. Each PHS organization has been requested to increase its minority performance to comply with the President's initiative.

Higher minority business goals have been established for each agency. This initiative will be monitored closely to ensure its achievement.

With regard to the grant process, many of our grants remain restricted by legislation to the participation of nonprofit organizations. However, whenever statutorily permitted, PHS research grants and cooperative agreements have been opened recently to profit organizations, including small and minority firms. Because this is a new area of participation for these organizations, grant announcements are being made in the Commerce Business Daily as well as the Federal Register. We are also coordinating the dissemination of information to small and minority firms regarding PHS grants and the grant process.

The Small Business Innovation Development Act of 1982, P.L. 97-219 was enacted to increase the involvement of certain research oriented small business and minority persons. PHS is implementing the first phase of this program through the grants process. In FY 1983, over $6 million in grant dollars is earmarked for use in compliance with this Act.

Question: Will your budget request for this function allow the PHS to operate on a current services level?

Answer: The 1984 request will permit the PHS Management activity to maintain the current services level and thus provide an effective overall management capability in headquarters and in the regions for administering PHS and OASH programs and special initiatives.

Question: In your narrative you mentioned your plans to continue your efforts to improve debt management procedures and cash management. Has this been a troublesome area? Please describe what you have done and plan to do to improve your management function?

Answer: This area has become significantly less troublesome in recent years as a result of the continuous attention and direction given by the Office of the Assistant Secretary for Health (OASH). During the past 2 fiscal years, OASH has established a number of high priority initiatives and has undertaken a number of management reforms to improve PHS performance in this area. During FY 1982, total collections were increased by 11 percent and the level of delinquent accounts was reduced by 38 percent.

Specific debt collection goals have been established for PHS agencies (e.g., targets for total collections, reduction of delinquent accounts, recovery of monetary audit disallowances). The PHS agencies are requested to develop special initiatives to address problem areas (e.g., revision of the regulations for the Health Professions and Nursing Student Loan programs to mandate reduced delinquency rates). OASH closely monitors the debt management and cash management activities of PHS agencies and meets monthly with representatives of the Office of the Secretary and OMB to discuss progress in meeting collection goals and completing specific initiatives.

A computerized management information system is being developed to facilitate the monitoring of PHS accounts receivable. Key data elements are entered into the system to enable PHS management to measure performance in this area. The system will prepare aging schedules for accounts receivable and permit comparisons of total collections, delinquent accounts, and audit disallowance recoveries for the current quarter with predetermined targets and with comparable figures for previous quarters.

OASH has conducted a series of management studies of specific programs and activities where the need for improvements to the debt collection process have become apparent and has issued a "Claims Collection Handbook" which provides PHS agencies with guidance concerning HHS policies and the "Federal Claims Collection Standards." In addition, OASH has begun to lay the groundwork for implementing the provisions of the Debt Collection Act of 1982. In some cases (such as contracting with private collection agencies), PHS agencies are already using the debt collection techniques provided for in the Act.

With regard to cash management, OASH has developed a Cash Management Action Plan with the overall objectives of expediting the deposit of monies due the Federal government and improving the scheduling and control of disbursements. In accordance with the Prompt Payment Act, the PHS agencies have been required to initiate programming changes and/or manual controls to payment systems to ensure that payments are made promptly. Beginning October 1, 1983, Treasury will require our agencies to use the Treasury Financial Communications System for certain payments.

PHS has been quite successful in increasing collections and reducing delinquent accounts during the past 2 years. OASH plans to continue providing overall coordination and direction to PHS debt management and cash management activities in future fiscal years to assure further improvements in these areas.

INTERNATIONAL HEATLH

Question: The International Health program was not funded in the OASH budget in FY 83. How many other agencies are involved in International Health activities and how are these activities coordinated?

Answer: Although the International Health program was not funded as a separate activity in FY 1983 it is being supported as part of the PHS Management Activity. All of the agencies of the Public Health Service have some level of involvement in international health activities. These activities are coordinated by the staff of the Office of International Health.

Question: What is the status of the Office of International Health? Who handles the functions carried out by this Office in past years?

Answer: The Office of International Health was transferred to the PHS Management activity in FY 1983 and consequently no longer appears in the budget as a separate line item. The Office continues to serve as the focal point for policy guidance and program coordi-

nation of international health activities conducted by the Public Health Service agencies.

Question. In your opinion, what has been the impact upon this Nation's concern for international health activities--of the loss of OASH support?

Answer: The Office of International Health funded through the PHS Management activity continues the international health coordination function, serves as the official liaison agency of the U.S. Government in relationships with international health organizations, is responsible for bilateral health, and scientific and technical agreements, and continues the overall management and coordination of the PHS Special Foreign Currency Program. OASH continues to provide support for these activities.

TERMINATION EXPENSES

Question: Please provide for the record:

-- Explanation of your termination request.

-- A detailed breakdown of the termination costs, including salaries and expenses. In addition, explain your calculations.

-- How many RIFs were there among PHS employees in FY 1982.

-- How many RIFs are planned for FY 1983 and 1984.

-- Please provide a breakdown of RIFs by grade and agency within the PHS.

Answer: The requested amount will fund costs of separating employees as a result of staff reductions in the family planning, migrant health, and black lung programs (which are proposed for consolidation into the primary care block grant); the elimination of the health planning program; and the reductions in the health professions program. Costs which must be funded include severance pay of employees who are separated; payment for earned annual leave of employees who are separated; salary costs for unbudgeted, filled positions for the period October 1, 1983 to Dec. 1, 1983; fixed overhead expenses for programs being reduced or eliminated; and unemployment benefits billed to the Public Health Service. These estimates are based on costs experienced in 1982. The following is a summary of the estimated expenses associated with these program reductions:

Severance pay.....	$2,867,000
Lump sum leave payments.....	1,982,000
Pay costs.....	2,599,000
Residual Overhead.....	602,000
Unemployment Benefits.....	1,650,000
Total.....	9,700,000

In 1982, exclusive of the PHS hospitals and clinics, there were 145 separations associated with the RIF conducted in the PHS. No separations are anticipated in 1983 as a result of RIF actions.

Until RIF procedures are initiated it is not possible to determine the grade of employees to be separated. We currently estimate that 54 separations would occur in OASH and 496 would occur in the Health Resources and Services Administration.

PHS COMMISSIONED OFFICERS

Question: Please explain the other new provision in your language to collect money for commissioned officers who are on detail.

Answer: The new provision permits PHS to bill non-DHHS agencies for the indirect costs such as medical care related to the assignment of commissioned officers to those agencies. At present PHS bills only for salary and benefit costs and the reimbursement is collected by the PHS agencies paying the officer's salary. The collections for indirect costs will be deposited in the Retirement Pay account.

Question: How many retired PHS commissioned officers will be receiving retirement benefits this fiscal year? Please describe the range of these payments and the reasons for this distribution?

Answer: In FY 1984 we expect to average approximately 2,000 retired commissioned officers receiving retirement pay. The monthly retired pay for FY 1983 has ranged from a low of $177 to a high of $4,725. Individuals on the low end of the range are typically those who retired before 1973 and those who have retired for medical disability. The high range is representative of a very senior officer with a lengthy career who retired around 1973 and has had retired pay adjustments which have exceeded normal annual pay adjustments.

Question: Why do PHS officers not contribute to their retirement? Has there been any discussions on requiring contributions? If so, please elaborate.

Answer: PHS officers, like those of the other uniformed services, do not contribute to a retirement system and are not vested until they have 20 years of service for normal retirement purposes. That is, they do not acquire any retirement value or incur any costs until that period of service. Presently, only about five percent of officers entering on duty ever achieve that period of service.

There have been many studies of the uniformed services retirement system which have considered, among other factors, a contributory retirement system and earlier vesting; however, none have resulted in changes. The issue appears to be on the agenda for the Armed Services Committees again this year.

Question: Is the optional survivors benefits program self-supporting from deductions or does the Federal Government supplement this program? What percentage of the benefits paid out are self-supporting?

Answer: For this account, the Survivor Benefit Plan has been completely self-supporting. In FY 1982 the total survivor deductions exceeded the annuity payments.

Question: Compare the cost of care provided under the PHS officers Dependents Medical Care program in uniformed services facilities with care provided under the program in private facilities.

Answer: The Department of Defenses has established an all inclusive daily inpatient rate in a Uniformed Services Medical treatment facility of $369 per day. According to Mutual of Omaha Insurance Company, the comparable cost in a private sector facility would be $413.

Question: Do participants in the Dependent's Medical Care program contribute to the cost of the program? If not, has there been any discussion about requiring co-payment?

Answer: For care in a uniformed services facility, the participant pays $6.55 per day for inpatient subsistence costs only. There is no cost for outpatient care in uniformed services facilities. In civilian hospitals, the participant pays either $6.55 per day or $25 per hospital stay, whichever is greater, for inpatient care through the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS). For civilian outpatient (CHAMPUS), there is a $50 deductible per patient or $100 per family per year, plus 20% of the allowable charge for dependents of active duty and 25% for retirees and their dependents. For care under the Program for the Handicapped (CHAMPUS), the amount the sponsor pays is on a sliding scale based on rank. To our knowledge, there have been no discussions regarding co-payment.

HEALTH BLOCK GRANTS

Question: During FY 1984, authorities for health block grants expire and at that time Congress will have to determine how effective these programs have been in meeting their various purposes and what kinds of changes might be required to make them more effective. Please describe the kinds of data you are collecting which will help us to evaluate the effectiveness of health block grants.

Answer: We will be able to use various data sources to provide information to the Congress for the health block grants. The States are required by statute to submit an annual report to the Secretary . The statutes also require that the States submit various reports with their annual application for health block grant funds. The Office of the Secretary/DHHS has a contract with the Urban Institute to provide State expenditure data on the DHHS block grants. The General Accounting Office is conducting a detailed follow-up survey on the implementation of block grants in 13 States. In addition, there are several studies being conducted outside the Federal government which we hope to use when they are available. The topics of some of these studies include: Mental Health Financing and Services in 18 States (Carnegie-Mellon University); State and Local Reactions to Block Grants in 14 States (Princeton University); Ten State Survey of Agencies at Sixteen State and City - County levels (American Public Health Association); and Public Hearings and the Maternal and Child Health Blocks (Intergovernmental Health Policy Project).

Question: What kinds of analysis of these data have you undertaken which will assist us with this evaluation and which will also allow us to determine whether the block grants have been more effective than their categorical program predecessors?

Answer: Since most of this data is currently being collected and reviewed prior to publication we have not initiated any analysis. The reports which the States provide to us are being reviewed.

Question: How do you determine whether States are complying with requirements that they use their allotments for purposes mandated by law and how do you determine that States use Federal funds to supplement, rather than supplant, State levels of funding for programs included in the blocks?

Answer: There are several mechanisms that are used to check State compliance with the statutory requirements for use of block grant funds. The reports contained in the State's application describe the intended uses of the grant funds the State will receive for the fiscal year for which the application is submitted. In addition, each State, also as part of its application, is required to provide certain assurances regarding its use of the funds. Finally, each State is required to submit an annual report on its activities, the expenditure of funds, and the purposes for which funds were spent.

In addition, the statutes for the Preventive Health and Health Services, Alcohol and Drug Abuse and Mental Health Services and Primary Care block grants require us to conduct investigations in several States each fiscal year on the use of funds in order to evaluate compliance with the statutes and the certification provided with the applications. One of the elements of our compliance review is to verify adherance to the statutory requirement that States use Federal funds to supplement rather than supplant State, local and other non-Federal funds.

A final method of monitoring the States use of funds is the required independent audit of State expenditures to determine States compliance with statutory requirements regarding the use of these funds.

Question: As you know, States are required to spend three dollars for every four Federal dollars received under the Maternal and Child Health Block Grant. What method do you use to determine that States are meeting this matching requirement?

Answer: The States are aware of the statutory requirement that they spend three dollars for every four MCH dollars received under that block grant. The audit of the States expenditures for the MCH block will be used to determine that States are meeting this requirement.

CONSULTANT SERVICES

Question: Although your program operations budget fell by about $5.5 million between 1982 and 1983, your consultant costs jumped from $2,945,000 to $4,380,000 this year and you plan to spend the same amount next year. Why has it been necessary for you to increase your consultant budget so sharply?

Answer: The majority of the increase is for evaluation of PHS programs. Funding for these projects is provided by all PHS agencies, not just the Office of the Assistant Secretary for Health (OASH). These resources are used to support a variety of projects that directly relate to the goals of the Public Health Service. Fiscal year 1982 was a period of significant programmatic change within PHS and was not representative of the normal level of consultant services activity. Programs have stabilized in FY 1983 and an adequate level of consultant services will be resumed.

OTHER SERVICES

Question: Dr. Brandt, the biggest increase in your budget is $18,627,000 for "Other Services". This is more than $11 million above the current level. Why such a significant increase? Let us have a breakdown of what is included in your "Other Services" budget for the record.

Answer: Of the $11,149,000 increase for Other Services, $9,700,000, or approximately 87 percent is for PHS termination expenses related to the anticipated reduction of 844 positions in the Public Health Service in FY 1984. The termination expenses are requested in conjunction with proposals to eliminate the health planning program; to incorporate a number of categorical programs into the Primary Care Block Grant in FY 1984 (i.e. Migrant Health, Black Lung Clinics, and Family Planning); and to reduce the health manpower programs.

An additional $834,000 is requested in Other Services for payments by the National Center for Health Statistics to States for vital statistical data previously provided at no cost to the Federal government.

The remaining increase of $615,000, or 5.5 percent, is for mandatory increases related to Service and Supply Fund, Federal Employee Compensation Fund, increased technical assistance activities, and increased review costs for additional grant applications.

Question: You are to be congratulated for reducing your standard level user charges at a time when these costs are being increased throughout government. How will you be able to cut $12,000 next year from the current level?

Answer: The standard level user charges have remained substantially unchanged. The reduction reflects a redistribution of space and an overall decrease in planned space utilization.

HEALTH SERVICES RESEARCH

Question: Dr. Brandt, on page 146 of your justification you state that by implementing generic drug substitution laws, approximately $3 billion in expenditures for prescribed drugs could be saved. Why aren't these laws being implemented?

Answer: While 49 States and the District of Columbia have passed generic drug substitution laws, there are wide variations in

these laws. Some merely permit substitution. Others require it. Some require substitution of a less expensive drug but only if it is stocked by the dispensing pharmacy. Some States do not place restrictions on drug substitutes. Many States provide lists of acceptable substitutes (positive formulary). Some States use a negative formulatory which simply lists unacceptable substitutes. Positive formularies encourage substitution even though many of these exclude several of the high volume drug entities.

The laws also differ on the ways that a physician can prohibit substitution. It has been shown that physicians seldom prohibit substitution if they are required to write in their own handwriting that substitution is not allowed rather than being permitted to simply check a box or sign on a line.

Legislation does not necessarily change long-established patterns of behavior of hundreds of thousands of providers of care and millions of consumers. Brand name drugs, at a cost of 20-25 percent more than the bioequivalent generic counterparts, continue to be ordered because neither the prescribing physician nor the dispensing pharmacist bear the financial risk of their decision.

Question: You are requesting $15,730,000 for health services research in 1984. The mission of the National Center for Health Services Research as set forth on page 149 of your justifications is to "improve the effectiveness, efficiency and distribution of health care services in this country." You give a number of examples of projects supported by the Center which point the way to reducing health care costs. However, as a practical matter health care costs have been rising at a far faster rate than the overall cost of living in recent years. Using this realistic measuring stick, wouldn't you say that the Center's work to date has had a negligible effect on health care costs?

Answer: Health care costs are in part driven by structural and functional characteristics of the health care delivery system which are amenable to change growing from knowledge developed through health services research. But they are also driven by other inflationary factors including energy, costs of capital formation, malpractice insurance costs and the use of life-saving technology which is expensive.

The National Center for Health Services Research is not a regulatory program and can neither legislate nor otherwise mandate changes in Federal reimbursement policies or how the public and private providers of health care behave. Neither is it desirable for NCHSR to lobby for changes. The Center can do a more effective job of disseminating the knowledge it develops to executive and legislative branch policy-makers and this budget request will support those activities in FY 1984 based on plans which we are currently implementing through both the User-Liaison Program and our publication strategy.

The User-Liaison Program has successfully convened workshops of State legislators and executive branch senior managers to provide focused and concentrated opportunities to provide information around topics where substantial money could be saved by effecting changes based on research findings. These have included long-term care, prospective payment and health maintenance organizations. Pending

syntheses of research findings--which will be the basis for future workshops--include State options for addressing catastrophic health expense, the supply and distribution of physicians, and State and local health planning.

Question: Can you tell us how much of your 1984 research grant and contract budget you intend to spend on health promotion and disease prevention?

Answer: NCHSR intends to expend approximately $1.4 million of its 1984 research grant and contract budget on health promotion and disease prevention. While this is a target for expenditure, the Center is in large part dependent upon investigator-initiated research. If scientifically meritorious research proposals addressing this area are not submitted, projected expenditures will change substantially. NCHSR will not support research which does not pass the test of scientific merit as determined by formally constituted peer review panels.

PREVENTIVE MEDICINE RESEARCH

Question: On page 151 of your justifications you list a number of preventive medicine research activities. However the list seems to cover treatment more than prevention. It includes research into ways to improve the packaging and distribution of medications and the development of protocols to aid in the monitoring and treatment of childhood diseases such as asthma. How can this be classified as preventive medicine?

Answer: There are three types of preventive medicine. Primary prevention seeks to forestall the occurrence of illness. Activities that focus on changing individual behavior that is harmful such as smoking or involve specific preventive measures such as immunization, fall into this category. Secondary prevention seeks to minimize or eliminate the potential sequela of an illness. Case finding and early treatment of such diseases as breast and cervical cancer fall into this group. Tertiary prevention involves efforts to restrain the progress of disease once the disease has manifested itself. It involves efforts to maintain a maximum level of independence and activity in the chronically ill.

Over the years the National Center for Health Services Research has supported research projects that address all three areas of prevention. For example, the Center has supported research to identify promising strategies for reducing the number of people who smoke. It supported the development and evaluation of the Health Hazard Appraisal technique that identifies individuals whose personal behavior places them at high risk. In the area of secondary prevention, it has supported studies of the cost benefit of mammography for early detection of breast cancer and pap smears for early detection of cervical cancer.

The projects to improve the packaging and distribution of medications such as those for hypertension and the development of protocols to assist parents in controlling asthma in children, examine problems in the area of tertiary prevention. Rigid adherence to therapeutic regimens to control hypertension can result in substantial increases in longevity and productive life in those with this illness. However, the poor and uneducated often have

difficulty following the complex therapeutic regimen that is required. NCHSR is exploring the possibility that patient compliance can be greatly improved by innovative approaches to packaging medications.

Childhood asthma is a chronic disease requiring frequent visits to the physician or clinic to deal with acute episodes. To the extent parents can be trained to recognize the early onset of asthmatic attacks and to dispense medications in an appropriate manner and at the appropriate times, acute episodes can be reduced in number and the costs of treatment can be minimized. The Center's study in this area of tertiary prevention is unique. The development of protocols to guide parents in dealing with this disease could well serve as a prototype and represents an innovative approach to dealing with chronic childhood illness.

NCHSR is planning efforts in FY 1983 and 1984 to increase its activities in the area of developing health status indicators which will be sensitive to the effects of health promotion programs and which will permit assessment of the post-effectiveness and efficacy of those programs.

USER LIAISON PROGRAM

Question: Dr. Marshall, page 152 of the justifications touches briefly on the Center's User Liaison Program for State and local officials. I notice that in fiscal 1982, workshops were held in States such as Maine, Florida, and Hawaii. How much did the Center spend in fiscal 1982 for these workshops and how many States were visited? Can you identify them now?

Answer: NCHSR User Liaison Program workshops are undertaken only at the specific request of State and local officials involved in policymaking that affects the planning, management, delivery and financing of health services in their jurisdictions.

Workshops are planned and sponsored jointly by NCHSR and various legislative and executive branch agencies.

State and local requests to NCHSR for such workshops always center around specific issues and problems of critical concern. These requests seek to create a setting in which the knowledge gained from research and experience can be applied to such issues and problems, and to bring together the key legislative and executive and officials with major responsibility in the areas being addressed by the workshops.

In fiscal 1982, nine such workshops were requested by various officials and were conducted jointly on the following topics:

- The Provision of Community-Based Long Term Care Services for the Elderly, requested and cosponsored by the Committee on Appropriations, House of Representatives, State of Connecticut, and the Department of Human Services, State of Maine, and held on October 21-23, 1981.

- The Provision of Community-Based Long Term Care Services for the Elderly, requested and cosponsored by the Agency for

Human Services, State of Vermont, and held on November 15-17, 1981 in Jeffersonville, Vermont.

o The Organization and Delivery of Rural Health Care Services, requested and cosponsored by the Department of Health and Social Services, State of Alaska, and held on December 8-11, 1981 in Anchorage, Alaska.

o Perinatal Intensive Care, requested and cosponsored by the Health and Rehabilitative Services Committee, House of Representatives, State of Florida, and held on January 12-13, 1982 in Tallahassee, Florida.

o Health Planning at the State and Local Level, requested and cosponsored by the Department of Health, State of Texas, and held on March 16-19, 1982 in Wimberly, Texas.

o The Organization, Delivery and Financing of Long Term Care Services, requested and cosponsored by the Office of the Governor, State of Hawaii, the Hawaii Department of Social Services and Housing, and the Public Health Committee of the Hawaii House of Representatives, and held on May 11-14, 1982 in Lihue, Hawaii.

o The Operations and Performance of Health Maintenance Organizations, requested and cosponsored by the Department of Health and Rehabilitative Services, State of Florida, and held on September 8-10, 1982 in Saddlebrook, Florida.

o Analysis of the Report of the Iowa Governor's Commission on Health Care Costs, requested and cosponsored by the Iowa Department of Health and the Iowa Department of Social Services, and held on September 20-24, 1982 in Ames, Iowa.

o Health Planning at the State and Local Level, a workshop sponsored in response to multiple requests for such an activity from State and local officials from Maine, Connecticut, New Mexico, Idaho, Michigan, Illinois, Arizona, Washington, Utah, Missouri, Colorado, Nevada, Massachusetts, Ohio and others, and held on October 18-22, 1982 in Rensselaerville, New York.

Officials from 21 states participated in the workshops undertaken by the NCHSR User Liaison Program in fiscal 1982.

In fiscal 1982, the NCHSR expended approximately $360,000 in the conduct of the workshops described above.

Question: Are these workshops funded entirely by the Federal government?

Answer: These workshops are joint efforts on the part of NCHSR and the various agencies serving as cosponsors. Senior executive agency officials and legislators devote a considerable amount of their time to the planning of these activities, and also make available to NCHSR the time of their staffs with respect to gathering relevant State and local data as background for these workshops. State and local officials participating in the workshops

also share in the costs associates with their travel and subsistence.

Question: How much do you plan to spend on these workshops in fiscal 1983 and fiscal 1984? I'd also like a list of the States involved.

Answer: During fiscal 1983, the following two workshops have been conducted to date:

- o On December 9-11, 1982 a workshop on hospital financing and reimbursement was conducted in cooperation with the Health and Institutional Services Joint Standing Committee of the Maine Legislature, the Maine Department of Human Services, and the Maine Health Facilities Cost Review Board.

- o On January 12-13, 1983 a workshop on the operations and performance of Health Maintenance Organizations was held in Ames, Iowa. It was requested and cosponsored by the Office of the Governor, the Health Policy Corporation of Iowa, and the Iowa Departments of Health and Social Services.

At this point in time, two additional workshops are scheduled for fiscal 1983. They are:

- o A workshop on health care cost containment to be held on June 10-12 in Owensboro, Kentucky and cosponsored by the Interim Joint Committee on Health and Welfare of the Kentucky Legislature.

- o A workshop on health care cost containment to be held in the State of Nevada in the Fall of 1983 and sponsored in cooperation with the Health and Welfare Committee of the Nevada State Assembly.

During fiscal 1983, the NCHSR plans to spend approximately $200,000 on the conduct of workshops for state and local officials.

Specific workshops have not been planned for fiscal 1984, although a number of requests have been received from various officials around the country. Our estimated cost of workshops in fiscal 1984 is $400,000.

GRANT PROGRAM

Question: Only $542,000 in Health Services Research funds will be spent on new grants and contracts next year. The bulk of your budget — $8.3 million — will support continuations. Furthermore, the average cost of continuation projects will rise from $137,500 currently to $166,100 next year while the average cost of a new project will drop from $149,700 to $135,500.

Why are you placing such a heavy emphasis on continuation grants and slighting new research, which seems to be more cost effective?

Answer: NCHSR will not slight new research. As needs arise, ongoing research (i.e., continuations) may be phased out in order to turn attention to research areas within the current policy

debates. In addition, NCHSR's new management practices will result in cost savings which may permit funding additional new starts within this request for 1984.

While NCHSR is committed to continued support of ongoing projects, recently it has adopted new internal management practices. As a result:

- o Ongoing and future research will become more user and product oriented. Emphasis will be placed on supporting research that will contribute substantially to current policy debates by filling in gaps in current knowledge.

- o Extramural research support will become more complementary to intramural research currently underway. Conversely, data resulting from intramural research projects will, as mentioned, be entered on to public use tapes for extramural research purposes and policy analyses.

In addition to the increase in the grant continuation costs, the 1984 level includes expanded contractual support for the preparation and documentation of public use files from the National Health Care Expenditure Study and the Hospital Cost and Utilization Project. The availability of these public use data files will allow those in the private sector interested in health policy issues to conduct their own analyses of data.

Question: What is the longest period over which you have funded a research project? What is the life span of an average continuation grant or contract?

Answer: The longest period over which a research project has been funded by NCHSR was 12 years. Under this grant, which was concluded in 1980, investigators conducted a longitudinal study of lifestyles. By surveying a study population for 10 years the grantee was able to examine the relationships between living habits and health. Present grant regulations (promulgated in 1978) limit all grants to a maximum of five (5) years funding and a maximum 6-month, no-cost extension.

NCHSR grants may run for five years. We have grants lasting from less than one year up to five. In Fiscal 1982 the average total life of a grant was 3.2 years. Grants are normally funded for 12-month budget periods. The life span of the portion of a grant that is a continuation (the period remaining after the first 12-month budget period) would be 2.2 years. With respect to contracts, the average life span is 1.75 years.

VITAL STATISTICS DATA

Question: Dr. Feinleib, the budget justifications reveal that some States now charge the Federal government for providing vital statistics. Can you tell us why they do and how many States are involved? Is that what the $834,000 proposed increase for this activity represents?

Answer: In 1973, NCHS began a cooperative vital statistics program under which the States processed their records and produced computer tapes which could be used to produce both national and State data, thus eliminating much duplication of effort and increasing the quality, uniformity, and timeliness of data for the States and the nation. Under this program, NCHS pays the States for part of their costs in collecting and processing the data and the States produce data tapes which meet NCHS specifications with regard to content, detail, and quality. Data tapes are currently being provided by States and registration areas on a funded/unfunded basis as follows:

Vital Statistics Subcomponent	States/Registration Areas: Funded	States/Registration Areas: Unfunded
Births & Deaths (Demographic Data)	44	4
Deaths	7	9
Abortions	15	1
Marriages	11	1
Divorces	8	1

Of the $.8 million increase being requested, $.4 million is necessary in order to continue supporting those States/registration areas previously funded at a level comparable to FY 1983. The remaining $.4 million is required to support previously unfunded States/registration areas which are now requesting payment for data previously provided at no charge.

SMOKING AND HEALTH INCREASE

Question: On page 164 of the justifications I note that--and I'll quote the sentence:

"The program increase also provides $362,000 for the comprehensive public information and education program and continued surveillance of the prevalence of cigarette smoking, the changes in the cigarette product and the attitudinal, behavioral and sociologic phenomena resulting from those changes"

Now, that's a rather ambitious goal for $362,000, Dr. Luoto. How will these funds be spent?

Answer: The Office on Smoking and Health is requesting a program increase of $1,362,000 which includes $1 million to conduct a teenage and adult prevalence, knowledge and attitude survey. The remaining increase of $362,000 includes:

-- $272,000 to continue and expand the government's public information campaigns in youth publications and in television.

  - o This increase will permit the Government to provide more material to high school and college newspapers and school counseling offices. After a period of six years of steady decline in smoking by high school students, smoking by high school seniors has now stabilized and additional effort in the field appears necessary.

- o An increase will help expand the Government's initiative with community health and medical agencies to develop local smoking and health information programs in co-sponsoring its television materials.

-- $90,000 for a contract with the World Health Organization to collate and disseminate worldwide information on smoking habits.

OFFICE ON SMOKING AND HEALTH

Question: Dr. Luoto, how long has the smoking and health program been in existence?

Answer: With the release of the Report of the Advisory Committee to the Surgeon General of the Public Health Service, a smoking and health organizational component was established. Since that time the Government has maintained a leadership role focusing national attention on the hazards of smoking for over 16 years.

Question: What are its accomplishments?

Answer: Since the inception of the Federal Government's anti-smoking efforts significant progress has been made and can be attributed in large measure to the renewed Federal emphasis which began with the creation of the Office on Smoking and Health, in 1978. For example:

- o In 1965, 42 percent of adults in the United States smoked. In 1980, the proportion dropped to 33 percent. Over 30 million Americans have quit smoking since 1964, 1.8 million of them quit during the period of 1978-1980.

- o Fewer men smoke cigarettes today, proportionately, than at any time since Government records began in 1955 -- perhaps since the 1920's.

- o Cigarette smoking among boys is lower today than probably at any time since the 1920's and 1930's and smoking among girls is now beginning to decline.

- o A substantial decrease has taken place in the tar and nicotine yields of cigarettes. Over 50 percent of all cigarettes consumed today yield 15 mg. or less of tar.

- o Since 1978, the number of research projects worldwide has increased with the major growth occurring in the behavioral sciences and other areas targeted by the Federal government as areas of need.

- o The Office on Smoking and Health produced the landmark 1979 Surgeon General's Report on the Health Consequences of Smoking, the most comprehensive document ever produced on the subject, the 1980 Report which focused on women's smoking and the developing lung cancer epidemic, the 1981 Report, which focused on the changing cigarette product and the existing evidence on the relative health risks

posed by the use of lower tar and nicotine cigarettes, and the 1982 Report on cancer, one of the most significant scientific and public health documents of the year. The 1983 Report will examine smoking and cardiovascular disease.

- Since 1979, the Technical Information Center has responded to over 15,000 inquiries from the scientific community.

- The program answered over 40,000 requests from the public in 1982.

- In conjunction with the Centers for Disease Control more than 120 smoking intervention demonstration projects have been initiated at the community level.

- State level smoking intervention and education activities have been initiated by each of the 50 State Health Departments.

- As the result of a cooperative initiative with health departments and other health agencies, individual smoking and health information/media programs have been instituted in over 30 of the largest metropolitan areas.

CONSULTANT SERVICES

Question: How much do you spend on consultants?

Answer: The Office on Smoking and Health depends on the expertise of a limited number of consultants to meet its goals and objectives. Consultants in the following areas of scientific expertise are necessary for fulfillment of the Office's mandate:

Pulmonary Diseases and Smoking
Cardiovascular Diseases and Smoking
Cancer and Smoking
Statistical Evaluation and Epidemiology
Behavioral Science

In FY 1983, the expenditure for appointive consultants is estimated at $20,000. The Office depends on these consultants only to the extent that similar subject matter experts are not available within the Federal government.

In addition, our public information materials are produced by an advertising agency and this activity is also classified as consultant services. In FY 1983, the contract will be approximately $500,000.

Question: What do they do?

Answer: The consultants provide the scientific expertise necessary for the production of the annual reports. Since 1967 the Department has been required to report annually to the Congress on the health effects of smoking. The Office has produced four major reports to Congress. This annual report is one of the most significant scientific and public health documents in the world.

AMERICAN LUNG ASSOCIATION

Question: How does the program interact with the efforts of the American Lung Association?

Answer: The Office on Smoking and Health is charged with coordinating the educational and research activities within the Department, with other Government agencies, and with liaison with the private sector. Cigarette smoking and the resultant health consequences involve more than fifteen different diseases addressed by at least as many different public and private agencies.

The Office on Smoking and Health works in cooperation with the three major voluntary health organizations, the American Heart Association, American Lung Association and the American Cancer Society. A number of public service announcements, for example, have been under joint Government and voluntary health agency sponsorship.

NATIONAL YOUTH SPORTS

Question: You are proposing legislation to extend the life of the National Youth Sports Program, which expired in fiscal year 1982. What happens if Congress does not reauthorize the program? Is it something the private sector might pick up?

Answer: We are requesting extension of title XVII of the Public Health Service Act, Health Information and Health Promotion, which would provide authority for OASH to assume responsibility for this program in 1984. In 1983, this program is authorized under the Community Services Block Grant set-aside. In the event that federal funds are not available, it does not at this time seem likely that private organizations would assume financial responsibility for the program. Private organizations do have a history of contributing much in-kind support such as equipment and supplies and efforts are being made to increase this support. However, the majority of the funding for the program is Federal and would be difficult to replace if it were to disappear.

Question: How many part time jobs will be created next summer if the program is reauthorized?

Answer: In 1983 and 1984 we estimate part time staff of 3,500 and 3,700 respectively.

STUDIES FOR PSYCHOTHERAPY

Question: During the past three Fiscal Years our Committee has expressed its interest in the Department taking a serious look at the extent to which effective forms of psychotherapy are being reimbursed under various federal health programs, especially Medicare and Medicaid. The Committee understands, for example, that the Department does not keep accurate statistics regarding psychotherapy reimbursements under these two programs. It is further the Committee's understanding that within the Department the National Center for Health Services Research has the responsibility for making policy recommendations for reimbursement of various health care technologies. Given continous testimony, which the Committee receives, that from 60-80 percent of the visits to physicians are for reasons that are primarily mental health related,

and that upwards of 25 percent of our nation may need mental health treatment, the Committee would appreciate learning whether any consideration has been given to directing the National Center to make this one of its priorities this Fiscal Year.

Answer: A series of studies regarding forms of psychotherapy is currently being carried out by Alcohol, Drug Abuse and Mental Health Administration. The results are being transmitted to Congress as they become available. Up to now HCFA has not asked the PHS to assess coverage of psychotherapy. If there are issues raised regarding Medicare coverage for psychotherapy the PHS will give them full attention. NCHSR makes recommendations only for coverage not for reimbursement.

HEALTH STRATEGY FOR THE PACIFIC BASIN

Question: For the past several years the committee has expressed its interest in the Department developing a coordinated approach to its responsibilities for the Pacific Basin region. What progress has been made to date in developing a comprehensive health strategy for the Pacific Basin?

Answer: During this fiscal year and continuing into 1984, the Public Health Service will conduct a thorough assessment of health care needs in the Pacific Basin. A joint effort conducted by the Office of the Assistant Secretary for Health together with our San Francisco Regional Office will produce a comprehensive report which will focus on the subjects of health services, facilities, manpower and training, public health practices, and program administration.

As a consequence of this effort activities will be undertaken to maintain and improve the health of Pacific Basin populations, while at the same time providing technical assistance and promoting self-sufficiency. In this endeavor we intend to involve the health leadership of the Pacific Basin and to apply the expert resources located at the health professional schools of the University of Hawaii.

SUPERFUND ACTIVITIES

Question: Please identify the HHS organizational entity responsible for the following statutory provisions required by the Superfund legislation, the number of persons working full time on these matters, and the amount of funding requested in the Fiscal Year 1984 budget for these specific functions.

Specifically, section 104(i) requires, among other things, the Secretary of Health and Human Services to:

-- create a national registry of diseases and persons who suffer serious illness after exposure to toxic substances, provide medical care and testing, including chromosomial testing and epidemiological studies, for individuals following emergencies caused by exposure to toxic substances, and

-- establish screening programs to determine the relationship between exposure to toxic substances and illnesses.

Answer: Since the enactment of Superfund, the health-related activities authorized by the law have been coordinated by the Centers for Disease Control and carried out by the appropriate program entities within the Public Health Service. The lead responsibility lies in CDC's Center for Environmental Health. The Center for Environmental Health has a 32 member staff assigned full time to investigating the possible link between human exposure to hazardous substances escaping into the environment from uncontrolled disposal sites or through accidental spills and adverse health effects. These investigations measure exposure levels, health effects, and include health advisories designed to limit or prevent further exposure. The Administration's budget for all of the HHS Superfund activities in FY 1984 is $1,905,000.

SUBCOMMITTEE RECESS

Senator WEICKER. The subcommittee will recess until tomorrow, April 7, at 8:30 a.m., at which time we will hear from the Social Security Administration.

And Dr. Brandt, thank you very much.

[Whereupon, at 10:10 a.m., Wednesday, April 6, the subcommittee was recessed, to reconvene at 8:30 a.m., Thursday, April 7.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1984

THURSDAY, APRIL 7, 1983

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, D.C.

The subcommittee met at 8:32 a.m., in room SD–116, Dirksen Senate Office Building, Hon. Lowell P. Weicker, Jr. (chairman) presiding.

Present: Senators Weicker, Proxmire, and Chiles.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

SOCIAL SECURITY ADMINISTRATION

STATEMENT OF NELSON SABATINI, ASSOCIATE COMMISSIONER FOR MANAGEMENT, BUDGET, AND PERSONNEL

ACCOMPANIED BY:

LINDA McMAHON, ASSOCIATE COMMISSIONER, OFFICE OF FAMILY ASSISTANCE

FRED SCHUTZMAN, DEPUTY DIRECTOR, OFFICE OF CHILD SUPPORT ENFORCEMENT

ANTHONY ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET, DHHS

PHILLIP N. HAWKES, DIRECTOR, OFFICE OF REFUGEE RESETTLEMENT, SOCIAL SECURITY ADMINISTRATION

INTRODUCTION OF ASSOCIATES

Senator WEICKER. The subcommittee will come to order.

Today, we will hear testimony on budget requests for the Social Security Administration, including the Offices of Child Support Enforcement and Refugees.

The lead witness is Mr. Nelson Sabatini, Associate Commissioner for Management, Budget, and Personnel for the Social Security Administration. And I gather you have got a seven-page summary statement along with a longer statement addressing specific appropriation accounts in detail.

Your entire statement will be included in the record, but you may wish to summarize it at this point.

I would be delighted to have you introduce your associates and proceed as you wish.

Mr. SABATINI. I am Nelson Sabatini.

I have with me today Linda McMahon, who is the Associate Commissioner of the Office of Family Assistance;

Mr. Fred Schutzman, who is the Deputy Director of the Office of Child Support Enforcement;

Anthony Itteilag, Deputy Assistant Secretary for Budget; and

Dr. Phillip Hawkes, the Director of the Office of Refugee Resettlement.

OPENING REMARKS

Our total appropriations request that we have before the committee today, Mr. Chairman, is for $22.8 billion. This includes $838.6 million for payments to the trust funds;

$1 billion for special benefits for disabled coal miners, the black lung program; $7.9 billion for the supplemental security income program; $7.1 billion for assistance payments program, including AFDC; $416.5 million for the child support enforcement program; $1.3 billion for low-income home energy assistance; $485.3 million for refugee and entrant assistance; and $3.7 billion for the limitation on administrative expenses.

A key point in our appropriation request is that the totals that I am talking about do not include the social security benefits, which are paid directly from the trust fund and are permanently appropriated.

Also, for the most part, the recent social security legislation is not reflected in this appropriation request. But the legislation will affect three of the accounts that we will be discussing today—the payment to the trust funds, the SSI account, and limitation on administrative expenses account.

We will be sending an amended request to the committee shortly, as soon as we have had a chance to evaluate the effect of this legislation more fully.

The total request of $22.8 billion is a decrease of $2.6 billion from the fiscal year 1983 level. This decrease is primarily because of the fact that in 1984, we will be paying 11 SSI checks as compared to 13 that will be paid in 1983.

The reason 13 will be paid in 1983 is that October 1 falls on a weekend, and we, therefore, will have to issue the check the day before that.

The appropriations also reflect the impact of proposed law in the assistance payments and child support accounts, and also a lower low-income home energy assistance funding level.

INITIATIVES REFLECTED IN THE REQUESTS

One of the highlights of our initiatives reflected in these requests is the continuation of our efforts to modernize our data processing system. And I would like to take this opportunity to thank the committee for the support they have given us both in terms of funding the systems in-

itiative and also allowing us to carry over funds so we can continue this very important endeavor.

The schedule that we are following toward implementation of our systems modernization plan is doing remarkably well. And we hope to continue this and meet all of the goals and objectives that we have set.

In addition, we are reflecting some changes in the disability program. We are budgeting for face-to-face interviews in our continuing disability investigations, to humanize this process, and make sure that people who are eligible continue to receive payments under the program.

We have tried to improve our disability case processing by establishing better communications with the State agencies that make these decisions for us, using better forms and instructions and improving their training.

We are also planning to implement the recently enacted legislation that requires a face-to-face evidentiary hearing at the reconsideration level and also the continuation of payments through the appeals level.

The appropriation request also reflects our continued efforts to effectively manage the agency's outstanding debt. Our efforts in this regard are three-pronged.

We are working to prevent the occurrence of debt.

We are improving our efforts to detect debt at the very earliest possible point.

And we also plan to continue our aggressive efforts to efficiently collect outstanding debts, at the same time seeing to it that the individuals' rights to due process are fully protected.

Thank you.

Senator WEICKER. Thank you very much.

SUBSEQUENT AUTHORIZING CHANGES

You are recommending including bill language to amend the Social Security Act through the appropriations process in order to make legislative savings of $722 million primarily in aid to families with dependent children.

What is the rationale for attempting to bypass the authorizing committees with this legislation?

Mr. SABATINI. Well, this is an executive branch policy that has been established, sir. And the reason for including the impact of proposed legislation in appropriation estimates is so these estimates reflect the total President's budget request, both current and proposed legislation.

This is why we are reflecting proposed law in the appropriations, because we fully intend to submit legislative proposals to the substantive committees for their action.

Senator WEICKER. I want to make it clear to you as I have to other agencies that have appeared before the committee that the chair will not—and I hope the committee would not, the subcommittee or the full committee—achieve any legislative change through the appropriations process. That is not our job.

Mr. SABATINI. I understand that. As I say, we do intend to submit legislation.

Senator WEICKER. I would only recommend because time is going to be running very short, if you have got legislation, you better get it in to that authorizing committee; and I mean fast.

Mr. SABATINI. We are in the process.

Senator WEICKER. Because it will not be done by this committee.

I just want to reemphasize that point so there is no mistaking what we have tried to set for the record.

LEGISLATIVE SAVINGS ASSOCIATED WITH AFDC WORK ACTIVITIES

You are assuming legislative savings of $3 million by permitting States to require parents of young children to register for the work incentive program if child care is available. How can you project legislative savings associated with a program you propose to abolish in fiscal 1984?

Ms. MCMAHON. I think that is stated the wrong way, unfortunately. What it should say is that that proposal would permit States to require parents with young children to participate in work activities. That would include participation in job search, WIN demonstration, community work experience activities if they exist. We have alternatives to the WIN program that allow States to require these people to participate in some type of work activity.

STAFF RESOURCES FOR SOCIAL SECURITY LEGISLATION

Senator WEICKER. The social security bailout legislation recently passed by Congress contains many complex provisions that appear to impose a heavy administrative burden on your agency.

What additional staff resources will be required to effectively implement the new social security legislation?

And if you are asked to absorb the additional work with no extra staff, from what existing activities would you most likely have to divert staff?

Mr. SABATINI. Well, we are in the process of analyzing the implications of that legislation right now. And we don't know, and we don't have in precise terms, the staff impact. A great deal depends on the extent of automation in utilizing implementation of this legislation.

We anticipate, and we hope, that we will be able to absorb the cost of the implementation activity in 1983 by utilizing what we have left of the contingency fund. I expect that for 1984, we will have to come before the committee and ask for additional resources.

In terms of work power, the activities that we are involved in in the agency today are so critical to assuring we provide a continued high level of service, and even an improved level of service over what we have been providing in the last couple of years, that it is difficult to say what things we could stop doing.

System modernization is absolutely critical to continuing the level of service we provide. Our program service centers are already overbur-

dened with work and working just incredible amounts of overtime to see to it that benefit payments are properly calculated and people are given credit for earnings they have had after retirement.

So my impression is right now that it would be very difficult to implement the legislation, especially the 1984 activities, without additional work power.

LOW-INCOME ENERGY ASSISTANCE PROGRAM

Senator WEICKER. Earlier this week, Secretary Heckler indicated she planned to submit legislation to target low-income home energy assistance appropriations on certain States with the greatest climatic impact as part of the rationale for the proposed budget cut.

Aren't you putting the cart before the horse to request that Congress cut low-income energy appropriations in advance of legislation being submitted, much less enacted, to concentrate funding on certain States?

Ms. MCMAHON. First of all, we have somewhat larger rationale in terms of the $1.3 billion. We feel that is a significant amount of Federal money to provide for a program that is in fact supplementing a number of programs—Federal, State, and private—to help meet basic needs, including energy needs.

Although we do feel that it would be better to target those limited resources more on States that have greater needs, we still feel $1.3 billion is the amount of money that we can afford to spend at the Federal level on this program.

Senator WEICKER. You have also answered my second question, which was: Would you still support a cut of this magnitude if the existing statutory allocation formula were not changed?

And you are saying you would.

Ms. MCMAHON. We had $1.3 billion in our budget last year, and we had not proposed to formulate an allocation change at that point.

Senator WEICKER. Under what you are recommending, for example, Connecticut would be cut from $41 to $27 million; Pennsylvania from $134 to $88 million; Michigan from $108 to $75 million. Wisconsin goes from $70 to $46 mllion.

Well, certainly that is a matter to be resolved as a matter of priorities, but I would doubt that either the legislation or the funding is going to change that much from the appropriation of a year earlier. We just have to see.

Senator Proxmire, do you have some questions?

Senator PROXMIRE. Yes.

Senator WEICKER. Go right ahead.

Senator PROXMIRE. Thank you, Mr. Chairman.

RATIO OF ADMINISTRATIVE COSTS TO BENEFITS

Mr. Sabatini, this last weekend, I was in Milwaukee at a home show that we have and I talked to a number of my constituents. These were people who were self-employed to some extent. They were moaning and groaning about the social security tax and the fact that they would have to pay a lot more.

They argued that they would be much better off—and I have heard this over and over again; I'm sure Senator Weicker as well as others have heard it, too—if they didn't have to contribute to social security. They argued that it should be made voluntary.

I know there are lots of answers to that argument. I am not going to ask you this morning to go into detail, but just as a matter of information, what is the ratio between the administrative costs of your program and the overall benefits?

Mr. SABATINI. The program, the ratio is approximately 2 percent.

Senator PROXMIRE. Two percent?

Mr. SABATINI. Yes.

Senator PROXMIRE. Is there any insurance company anywhere that has anything like that kind of a record? Do you or any of your colleagues have any idea how this would compare with the administrative costs incurred by insurance companies?

Mr. SABATINI. No; I wouldn't know that, Senator.

Senator PROXMIRE. Would you, sir?

Mr. SCHUTZMAN. No, sir.

Senator PROXMIRE. I thought I saw a glimmer in your eye.

Mr. SCHUTZMAN. Well, I think that——

Senator PROXMIRE. You go ahead.

Mr. SCHUTZMAN. In one of my former positions, I was involved in testifying in front of this agency. And we did look into it because that question came up before. In fact, I visited Mutual of Omaha, and they said their administrative expenses run about 30 percent.

Senator PROXMIRE. Thirty percent? I think that is about what I would expect.

Mr. SABATINI. The 2 percent we use in administrative costs is less than the commission they pay agents for the sale of policies.

Senator PROXMIRE. Well, I didn't have this information. Now I have. It is very helpful.

Now, let me get into some of the details of your budget.

AFDC ADMINISTRATIVE COSTS

The chart on pages 125 and 126 of your justification shows a wide range of State and local AFDC administrative costs paid by the Federal Government.

For example, the State of Washington would receive $20 million in 1984—about 13 percent of total costs. On the other hand, my own State of Wisconsin would receive only $12,481,000 to administer a much larger program—about 4.5 percent of total costs.

What is the reason for that differential? Why should the State of Washington receive more for administrative costs than Wisconsin when Washington has a much smaller program? Their administrative costs as a percentage of total costs are almost three times higher.

Ms. MCMAHON. We have been looking at a variety of factors that go into administrative costs per case. It is very difficult to come up with actual correlations as to why one thing happens in one State and one thing happens in another.

As you are aware, States have very different factors to deal with in terms of cost allocation: whether they are rural or urban populated, the sophistication of the State government, whether they have manual or automated systems, whether they have integrative programs, whether they have a case worker who handles food stamps, AFDC, and medicaid, or whether they have specialized case workers. There are a whole variety of factors that affect administrative costs per case.

We have had an effort for about 3 years now in the Office of Family Assistance, looking at performance standards of States by what they do, how they carry out the program, what is their error rate, do they get their hearings done on a timely basis, do they get their applications processed on a timely basis, and so forth.

We have found even in that review process that we can't come up with very good correlations as to what makes these things go together.

EFFORTS TO REDUCE AFDC ADMINISTRATIVE COSTS

Senator PROXMIRE. May I ask you this: What incentives do the States have under the existing system to reduce their AFDC administrative costs?

Ms. MCMAHON. We match their costs at a 50-percent rate which means they have to certify the availability and intention to spend $1 before we will match it. There is a certain sense of control there because they have to come up with those dollars up front.

We have found, for instance, the productivity is higher in States that have lower State budgets to work with. They have less money; they have to be more productive. The fact that States don't have a lot of money available to run these programs is one of the better incentives to improve administration.

Senator PROXMIRE. Are there any other incentives you think might be more effective? There seems to be a wide discrepancy in administrative costs.

Ms. MCMAHON. We have had several GAO reports that point to some kind of a productivity measure, some kind of a set limit on administrative cost per case. We have responded to that report and said basically that it is very difficult to come up with a number. States report on what the period of time is between when they get an application and process it and what they go through in order to process it. Reporting periods are not the same across States.

We have a contract this year to look at State data, its validity, and how we can make it more precise across States. So possibly we could come up with something that could limit administrative costs across the States to a realistic number.

Senator PROXMIRE. Will you let us know if you make a decision in that area?

Ms. MCMAHON. Be glad to.

SSI OVERPAYMENT RECOVERY

Senator PROXMIRE. About $180 million in SSI benefit overpayments has been owed to the Federal Government for a year or more. Of course, many of the debtors are quite poor—I suppose most of them are—and I am not suggesting you push them to the wall. But can you tell me what steps you are taking to recover this delinquent debt?

Mr. SABATINI. Well, last year was the first year of major focus of management attention on debt management. Overall, we have increased our level of collections from about $600 million to approximately $1 billion last year.

We have taken several steps to continue that effort. One is just giving more management attention to this workload and seeing to it that cases that involve overpayments are processed and processed timely.

Senator PROXMIRE. Do you have any procedure in place for assessing the estates of deceased beneficiaries?

Mr. SABATINI. The statute—title XVI—allows us to assess the estate of deceased beneficiaries. In fact, Senator, people who are eligible for SSI are by definition very needy, and very few of them have any estates.

Senator PROXMIRE. You are planning to spend about $900 million in fiscal year 1984 for the costs of administering the SSI program.

Your administrative costs have hovered around 10 percent of total SSI costs over the past few years. Why are your administrative costs such a large percentage of your program costs in view of the fact that the Social Security Administration's overall administrative cost percentage is so low?

Mr. SABATINI. The primary reason for that is the benefit amounts in SSI are much smaller than they are in the title II program so that the administrative costs will naturally be a greater percentage.

In addition, the program itself is significantly different from the trust fund programs in that it is much more sensitive to change because it is a need-based program. It requires us to spend time to investigate income and resource levels.

And also, the SSI program is predominantly a disability program. Processing disability cases is much more time-consuming and costly than it is for nondisability cases.

DECLINE IN SSI ROLLS

Senator PROXMIRE. You indicate on page 52 of your justifications that the average number of SSI recipients is expected to decrease by about 3 percent in 1984, yet the claims processing workload is expected to increase.

In other words, you think the number of recipients will go down, but the processing workload will go up. Tell us why that will be.

Mr. SABATINI. Well, the decrease, the decline in the SSI program, is one that is going—it is a trend line that has existed for some time. It is not unique to the SSI program; it existed prior to the enactment of the SSI program when these programs were administered with old-age assistance programs.

It is due primarily to the fact that as the social security—the trust fund programs—benefit levels increase and more people have connection with the work force, there is greater eligibility under title II and, therefore, a declining population in the SSI aged rolls.

Senator PROXMIRE. Yet, your claims processing workload is scheduled to go up.

Mr. SABATINI. The claims processing workload includes the work that is involved in maintaining changing benefit rolls.

Senator PROXMIRE. Why are your SSI work-years decreasing by 1,031 at a time when permanent positions are scheduled to go up by 400? Your SSI work-years are going down.

Mr. SABATINI. Yes, sir.

Senator PROXMIRE. Yet, your permanent positions are scheduled to go up.

Mr. SABATINI. Well, the SSI work-years are going down because of a decline in the rolls, some efforts we are taking to be able to process that workload more efficiently, better targeting of our redetermining efforts and involvement with an interface with the Internal Revenue Service to try to identify undetected bank accounts.

Our overall workloads in other areas throughout the agency are increasing.

Senator PROXMIRE. But your permanent positions will go up at a time when your average number of recipients will go down, right? This is all within the same area.

I'm talking about the information set forth on page 233 of your justification.

A table on this page indicates permanent positions will increase by 400 while work-years will fall by 1,031, a big drop.

Mr. SABATINI. What we are asking here is for an increase in the authorized position level in that a large portion of our work force currently exists in the field organization. For example, about 18 percent of that work force is in the all other category of positions. These include part-time, temporary, and term employments.

Having that size work force with that kind of mix has caused us problems in our field offices. And what we are asking for is an increase in the level of permanent positions so that we can convert some of these people and have more flexibility in terms of our management.

Senator PROXMIRE. Mr. Chairman, could I just ask Tom van der Voort to follow up on that?

Senator WEICKER. Yes.

Senator PROXMIRE. Go ahead, Tom.

Mr. VAN DER VOORT. One question is: Aren't your permanent positions with all the benefits, including health benefits, more expensive?

Mr. SABATINI. No.

Mr. VAN DER VOORT. With a decreasing benefit caseload, it doesn't make sense to be increasing permanent positions. Those trend lines seem to be going in opposite directions.

DIFFICULTIES IN RECRUITMENT

Mr. SABATINI. What we are asking is flexibility to have more full-time permanent people—having a large portion of the work force in this all other category causes us a number of problems. One, in terms of our ability to recruit people and bring them into the professional level entry positions, when the only thing, the best thing, that we have to offer is either part time or temporary or term-type employments.

And while the work force is remaining fairly stable——

Senator PROXMIRE. I thought that in this job market there were a lot of capable people available, more than ever before, at least more than in the last 10, 15, or 20 years.

Mr. SABATINI. The job market doesn't really—the availability of people doesn't really reflect the difficulties we are having in recruitment. For instance, in certain areas, we have extreme difficulty recruiting people that we can bring into our systems area.

Senator PROXMIRE. I recently talked to a group of teachers at a Wisconsin college, and it is a fine college, although small. I think about 100 students are graduating. This group has received only two job offers at this time. Three years ago, most of them had job offers.

So the number of young people graduating from college and eager to go to work—trained, skilled young people—is high.

Mr. SABATINI. I think our recruitment efforts would be a lot more successful if we were able to offer these people permanent positions.

In addition, we have a sizable work force of people that we have recruited who are sitting in these temporary or term-type appointments. We have invested a great deal of time, money, and capability in training them, people who are capable of helping the people, the productivity of the agency. We would like to sort of get them off this hook where they really don't know if they have the opportunity to build a career within the agency.

So what we are asking for is flexibility to move those people into permanent-type positions.

Senator PROXMIRE. Thank you very much, Mr. Chairman.

I have some more questions for the record.

Senator WEICKER. Thank you, Senator Proxmire.

Senator Chiles.

FISCAL YEAR 1983 TARGETED ASSISTANCE

Senator CHILES. Thank you, Mr. Chairman.

Dr. Hawkes, in the 1983 continuing resolution, Congress appropriated $75 million for targeted assistance for refugees and entrants. A conference agreement was reached to set-aside $35 million for refugees, mostly in California, $35 million for entrants, mostly in Florida, and $5 million for the heavily impacted school district in Dade County, Fla.

I understand the Office of Refugee Resettlement issued regulations on March 3 for allocation of the refugee portion. I assume those funds have been released.

You have not issued yet guidelines for the allocation of the entrant funds, nor do we see any sign of release of those funds by the end of the third quarter.

In fact, I am told that you intend to allocate only $18 to $19 million of the remaining $40 million for entrants.

The targeted assistance program was worked out with Secretary Schweiker, and Congress received his commitment and approval of the conference agreement. Why haven't these funds been released?

Dr. HAWKES. Senator, I am not aware of language that specifically tied $35 million of the $75 million to entrants. My understanding was that of the $75 million, $5 million of that was targeted to entrant education in such a manner that Dade County schools will receive that.

The other $70 million was for refugees and entrants. We have an eligible population of about 605,000 refugees and entrants of which 27 percent are entrants. Therefore, we determined to use 27 percent of the available funds then for entrant-targeted assistance.

There was no refugee-targeted assistance last year. And so it seemed appropriate that the first announcement would be for refugee-targeted assistance. That was announced on March 3.

We do expect to have those funds available by the end of the third quarter. The announcement for entrant-targeted assistance is in the final stages of clearance at this time and will be in the Federal Register shortly.

Senator CHILES. Well, I think that the agreement reached by the conference was clear to everybody involved. And I think Secretary Schweiker assured us that he would use his discretion to allocate the $35 million for entrant assistance.

You have the regulations that were used to allocate the funds last year. Why is it necessary to develop a new set of guidelines?

Dr. HAWKES. Well, Senator, last year, there was $35 million made available for entrant-targeted assistance. Of that amount, the State of Florida received $31 million. That money was used to offset the effects of the policy change in which special refugee benefits were reduced from 36 to 18 months.

The impact of that policy change occurred last April and May. We believe that the money that was expended last year under targeted assistance did adequately offset that impact.

Nearly 90 percent of the population of entrants becomes time expired in June, when they will reach the Federal 3-year limitation. We would like this year to target this money specifically toward self-sufficiency, the development of jobs and economic development.

The continuation of reimbursement for medical costs would, for instance, not be within the provisions of the Refugee Act which says that such reimbursement is limited to 36 months.

Senator CHILES. Actually, it was Secretary Schweiker himself that had the idea of providing assistance for medical costs after seeing the problems that were occurring in Jackson Memorial and the hospitals down there. And the problems that were occurring are the result of the paperwork and all other problems in trying to meet the medicare and medicaid redtape with refugees.

And he is the one that suggested that we set up this and then have contract authority and handle it on that basis. So is this now the Department reversing that?

Dr. HAWKES. No, Senator. We did that—in fact, we went back through our own rolls in order to verify a large number of claims that were presented to us by Jackson Memorial Hospital. I think around $14 million of the $31 million that we gave to Florida last year was in fact used to cover additional medical expenses.

I wasn't aware that the Secretary made any commitment to cover medical costs beyond 36 months of Federal responsibility.

Senator CHILES. Of course, that is why it was in the targeted assistance. And that's why it was put in that way. And you still haven't covered the 36 months yet.

Dr. HAWKES. Well, sir, last year's targeted assistance funds run through May 31, 1983. By the end of the third quarter of the Federal fiscal year, about 90 percent of entrants will be time expired.

Senator CHILES. Well, Jackson Memorial Hospital has treated and continues to t[illegible] housands of indigent Haitians and Cuban entrants. Those are peo[illegible] that are dumped on Florida by Federal policy and are not a responsibility of anything happening in Florida.

And even with the assistance that we receive, Jackson Memorial continues to run millions of dollars in the red.

You know, this is a Federal responsibility. Why should the State of Florida—we aren't the ones that asked or allowed the refugees to come into the State. So why should the State and the city and Dade County have to pick up those funds?

Dr. HAWKES. Well, Senator, that is a good point. I think, though, that the act specified a Federal responsibility of 3 years. And if we are going to extend Federal responsibility for such things as medical costs beyond 3 years, then it would take a change in the Refugee Act.

I don't think I have the authority at this time to use funds appropriated under that act to extend Federal responsibility beyond the law.

Senator CHILES. We are talking about money that Congress put in—specifically the $70 million which is outside and different from that act. You are talking about changing your regulations to knock out health assistance where the Congress has provided the money for those funds. I think it is totally different, what we are talking about, in the act.

I understand that $5 million in impact aid assistance to Dade County is in the process of being transferred to the Department of Education for release. I have heard that these funds should be released by the end of the month. Is that correct?

Dr. HAWKES. That's right, sir.

LOWRY AMENDMENT FUNDING

Senator CHILES. Under the so-called Lowry amendment, Congress appropriated $20 million for refugee and entrant assistance to States caught in the bind of continued cash and medical payments to certain refugees and entrants after Federal regulations changed, ending Federal reimbursement of those expenses.

The original intent of that amendment was to fully reimburse the States for expenses incurred during the transition period. Certainly the administration agreed to fulfill that commitment.

I understand those funds were allocated, but fell short of full reimbursement to several States. Florida has incurred about $2 million of unreimbursed payments. What is the total amount that States would be due if full reimbursement were made?

Dr. HAWKES. Senator, a little over $7 million has not been reimbursed to the States.

Senator CHILES. Does the administration still support the policy of reimbursing these States for their expenses over which they had no control during the change in regulations? Or has the administration reneged on that?

Dr. HAWKES. No, sir. The administration published a regulation that changed the policy which a majority of the States were able to comply with in a timely manner.

Senator CHILES. You published a regulation changing a policy. Is that reneging?

Dr. HAWKES. No, sir. It was not. There was no intent in that policy change to renege on any Federal commitments.

In fact, we continued to reimburse 100 percent of State costs within available appropriations. We paid 100 percent of the States' costs for April, and we paid all costs for those States that were under court order to extend their benefits beyond April.

After paying April and court-ordered costs, we divided up the money left over on a proportionate scale which left several States a total of about $7 million short. We don't have $7 million at this point to reimburse States for the remaining delayed costs.

Senator CHILES. But do you support the policy of fully reimbursing States for their costs incurred?

Dr. HAWKES. Yes, sir. It has been the intent of the Department.

STATE PROGRAM COSTS IN FISCAL YEAR 1983

Senator CHILES. We are now into the third quarter of fiscal year 1983. In the first two quarters, Florida incurred $9.3 million in cash expenses for entrants. The State has received $6.2 million in reimbursement to date.

Florida has spent $7 million for entrants' social services and received $6.7 in reimbursement. The tab for refugee cash and medical has grown to $4 million, and we received $1 million.

The cost of refugee social services has been $2.8 million, and we have gotten $3 million back in that. So I see a shortfall of $6.2 million in Florida.

What are your plans and schedule for meeting that shortfall?

Dr. HAWKES. Senator, we made an initial social service award and then allowed Florida to use over $1 million of unexpended funds from 1981 to meet their current costs of social services.

We are working with the State on the other cost areas. The first quarter expenditure reports for cash and medical assistance showed a significant increase in administrative costs, which were about 27 percent. And that was unexpected.

There was also a much higher than anticipated level of medical claims. We are working with the State to reimburse their allowable costs. And we certainly intend to reimburse those 100 percent.

Senator CHILES. Thank you, Mr. Chairman.

SSA'S COMPUTER PROBLEMS

Senator WEICKER. Thank you very much, Senator.

Last fall, Commissioner Svahn was quoted in the press as stating that Social Security's computer problems have become a more severe problem than the program's funding difficulties. Would you like to comment on that?

Mr. SABATINI. Well, the data processing capacity that we have had at the Social Security Administration, I think, has been described not only by the Commissioner, but by the General Accounting Office and several other organizations as being inefficient, outmoded, and archaic.

We had been working with data processing hardware equipment that was so old, it was no longer even being manufactured. We were buying machines on the market so that we could hold them and salvage them for parts.

Our software development was undocumented and inefficient.

PROGRESS ON SYSTEMS MODERNIZATION PLAN

Approximately 1 year ago, the Commissioner announced a 5-year systems modernization plan that was designed to take us from survival to the state of the art.

It is a very ambitious plan. And thus far—we submitted a report from this committee, detailing our progress. But I can tell you that we are making remarkable progress. We are on schedule, and we hope to be able to reach the state of the art in the very near future.

Just a few highlights of some of the things that have happened over the last year. We now have on board a systems engineering and information contractor to help us with the design and implementation of the plan. We have purchased four new main-frame computers. Two of them will be linked together as a multiprocessor designed to enhance our telecommunications network and our field offices.

We have a new machine that will increase and enhance our time-sharing testing facilities.

And we also have an economic replacement of a large Univac mainframe to improve our administrative systems capacities.

We are also in the process of installing a major acquisition of high-speed, state-of-the-art disk equipment that will enable us to start moving our master records on the high-speed disk and then give us the ability to start manipulating our records and our record formats so that we can reach a point where we have an effective data-based management system and improvement in just the overall efficiency of our operations.

SECURITIES AND EXCHANGE COMMISSION INVESTIGATION

Senator WEICKER. The press has reported the Securities and Exchange Commission is suing a firm for using deception to win an $84 million contract from the Socia. Security Administration. Reportedly, an empty box with flashing lights was represented as being a system to prevent unauthorized access to confidential data in computers.

Now, I would like to know how an agency as sophisticated as Social Security Administration could be fooled by such deception.

Mr. SABATINI. Well, I was advised last night, Senator, by the Inspector General that the Securities and Exchange investigation is going to be presented to a grand jury this morning. And in light of that, the advice was not to comment on the issue.

Senator WEICKER. To what extent does this particular situation delay your 5-year plan?

Mr. SABATINI. This situation is really divorced from our 5-year plan. The equipment that is in question has been installed and is functioning. And it is basically the terminals of that telecommunication network.

The primary emphasis of the 5-year plan is the upgrading of our centralized capacity in terms of state-of-the-art hardware. And equally important, I would point out, the plan is not just a plan designed to go out and buy more hardware. The key element of the plan is to modernize our software development and put the kind of disciplines in software development that have been lacking in the agency.

MANDATORY AFDC WORK PROVISION

Senator WEICKER. Your budget assumes a $275 million savings based on the assumption that legislative bill language will be included to require welfare recipients to participate in job search and further require all employable recipients to work.

How realistic is it to assume such savings when the administration is still projecting unemployment to remain near 10 percent and when other parts of the budget cut Federal support aimed at helping the unemployed find work?

I specifically cite as furtherance of that statement the Job Training Partnership Act cut by $333 million, the work incentive program cut by $270 million, social services block grant cut by $175 million, community services block grant cut by $382 million, vocational and adult education cut by $323 million.

Therefore, under the various work programs, those that would receive assistance from the Federal Government are cut by $1,483 million.

And certainly I saw the latest figures indicating there was a drop of one-tenth of 1 percent in unemployment. But I don't see anything in either of the Federal support figures or the unemployment figures as a whole which would give rise to this kind of assumption.

Maybe you would like to explain it.

Ms. McMAHON. Yes, sir. We have experiences in the last year or two with community work-experience programs and up front job search activities for welfare applicants and recipients. We have found that in spite of relatively high unemployment in certain areas that many individuals who do engage in job search prior to actually going on welfare do find jobs. For instance, the State of Oregon had over a 10-percent unemployment rate, but 10 to 15 percent of their caseload dropped because applicants were required to look for work between the time of application and actually going on rolls and found jobs.

In four States right now that are——

Senator WEICKER. Does that have anything to do with possible recovery in the housing industry and the resumption of work in lumber camps?

Ms. McMAHON. This was better than 1 year ago. We are just looking at where unemployment was and the fact that during that period of unemployment, people were still able to find jobs.

In New York, North Carolina, West Virginia, and Oklahoma right now, we are running community work experience programs. The levels of unemployment are different in different areas, but their experience is similar to other areas of the country. They are finding that 20 to 30 percent of the people who participate in these work programs find employment.

We see on the basis of evidence from these programs that because these people were in, I think, what they call the secondary labor market and that is not where the highest unemployment is occurring. Jobs are available. If these people are involved in work activities, they get experience, they are exposed to the job market, they are given some skills in just being able to participate in a work environment, and they are able to find jobs.

Senator WEICKER. Well, it seems to me that again we have to deal with what the law is.

ASSUMPTIONS UNDERLYING AFDC LEGISLATIVE SAVINGS ESTIMATES

It also seems to me as a matter of good fiscal practice that assumptions certainly fall into that category.

And if anybody, it seems to me, has it incumbent on them to engage in tight fiscal practice, your agency has that imposed on it. And I just think that $275 million is a huge assumption. It flies right in the face of everything that we see around us.

Ms. McMAHON. We feel that we used fairly conservative estimates in terms of the number of people who are deterred from going on welfare.

If they are going to have to be involved in the work activity, they will go out and find a job. In fact, we found some people actually had jobs and weren't reporting earnings, and decided to keep their regular job rather than go in for work absenteeism.

EXPERIENCE WITH AFDC WORK PROGRAMS

Senator WEICKER. Don't you agree that it would be better to have the experience in hand before you make this kind of an assumption?

Ms. MCMAHON. We have experience. We have operational experience. Twenty-five States already have programs up and running or are planning to implement those activities. We have three States that are currently doing employment search and a number of those activities are planned in other States.

There have been different kinds of work activities that have been available for a number of years, and States have run these programs.

The Federal Government has helped pay for them because they have been granted waivers that were reviewed by the Federal Government. We think we have a fair amount of experience.

Senator WEICKER. GAO in its January 1983, report disagrees with you and says it is too early to make judgments.

Ms. MCMAHON. I think it is too early to make the judgments that rely on big social research-type studies. But I think you can look at what is actually happening to the individuals, their reactions to the programs, and the fact that 20 to 30 percent of community work experience program participants in these four States are entering employment.

PROPOSAL TO ABOLISH WORK INCENTIVE PROGRAM

Senator WEICKER. Why are you proposing to abolish the work incentive program which helps welfare recipients find jobs in favor of an as yet unauthorized workfare proposal?

Ms. MCMAHON. The work incentive program has pieces to it which we feel were successful. Those are job search and community work experience type activities. We are maintaining those activities in our proposals. There is also the Job Training Partnership Act which is going to target money for training individuals.

The work incentive program itself, in total has a number of problems with it, not the least of which is dual agency responsibility. In fact, that GAO report pointed out that of those people who participated in or were required to register, about 50 percent never engaged in any activity other than a paper process.

Of those who engaged in any work activity, who actually found jobs, 70 percent of them said it had nothing to do with the WIN program; they would have found those jobs anyway.

We got down to a very small number of recipients who were impacted by the program in terms of actually getting a job. So looking at all the problems of the WIN program, we said, "What is good about the program? Let's take that out, run it under the welfare system, and get rid of this dual agency program and have a more efficient, effective program."

STATE PERFORMANCE IN CHILD SUPPORT PROGRAM

Senator WEICKER. I note there is a wide disparity that gets to the point Senator Proxmire raised in another area, between States' performance under the child support enforcement program. And some States such as Connecticut and Michigan return more money to the Federal Government than they receive for administrative costs. Others such as California have Federal administrative costs far in excess of the Federal share of collections.

Why is there such a wide disparity in State performance under the child support enforcement program?

Mr. SCHUTZMAN. Senator, on an overall basis, the child support program has done well in the past, but you are correct, and we have pointed that out to Congress last year, and we are doing it again this year.

We have proposed to change the financing of the program to a performance-funding based program in which the administrative costs of the program would be taken out of the AFDC collections. Any net would be shared between the Federal Government and the States.

In addition, independent of the Federal share, the Federal Government would pay performance moneys to the States for those States that increase their collections, or have good cost-effectiveness ratios, and who do some collections for non-AFDC families.

The reason that we feel there should be a change in the funding is that there is little or no incentive for States to improve their program because States with poor performance can still make a profit while the Federal Government subsidizes their program.

Let me give you an example. In the 10 worst States the cost-effectiveness ratios are 0.49, which means that for every dollar they spend, they collect 49 cents in AFDC.

If one looks at the current funding, the taxpayer is losing 51 cents out of that dollar. The States are making 2 cents. And it is costing the Federal Government 53 cents.

If Congress accepts our proposal and passes it, the example I cited would cost the State 25 cents, the Federal Government 25 cents, and, therefore, would be an incentive for the State to improve.

On the other hand, the 10 best performing States would stand to benefit by our proposal and would increase the revenue to the States.

VARIANCE IN STATE CHILD SUPPORT COSTS

Senator WEICKER. I notice, just to cite five States in this area of child support enforcement, in California, the Federal share of administrative costs is, rounding off, $86 million; the Federal share of collections is $54 million.

Florida is $11 million as the Federal share of administrative costs; the Federal share of collections is $7 million.

On the other hand, Connecticut's Federal share of administrative costs is $6 million; the Federal share of collections $7 million.

Wisconsin, the Federal share of administrative costs is $13 million; the Federal share of collections $17 million.

I just think that is wild.

PERFORMANCE-FUNDING IN CHILD SUPPORT PROGRAM

Mr. SCHUTZMAN. We agree with you. And that's why we have proposed this performance-funding approach.

Senator WEICKER. Are you asking for this legislation before the Finance Committee?

Mr. SCHUTZMAN. Yes; the legislation is still in the final stages of clearance within the administration and will be coming forward shortly.

Senator WEICKER. I understand you again have had this in bill language before this committee.

Mr. SCHUTZMAN. Yes.

Senator WEICKER. As much as I would like to see it changed, it isn't going to go in this committee.

Incidentally, just out of curiosity so we can all assess the changes of this situation, have you counted up the numbers as far as the States are concerned, how many are making money on this and how many are swinging their weight? Because that is going to determine votes out there on the floor.

How does it break just among the 50 States? How does it break now?

Mr. SCHUTZMAN. There are 19 States in fiscal 1982 that spent more than they collected.

Senator WEICKER. OK, 19 spent more than they collected.

Mr. SCHUTZMAN. Which you know really furthers the point that you were trying to make earlier that we think that——

Senator Proxmire. Does that mean 31 States collected more than they spent?

Mr. SCHUTZMAN. There are 54 jurisdictions, including some of the territories; that is correct.

Senator WEICKER. It doesn't sound too bad.

Senator PROXMIRE. You have the votes?

Senator WEICKER. There is only one problem. My staff has just informed me we have the votes in overall function, but it has to be pointed out 2 of those 19 States that do well by the present system are Kansas and Louisiana.

Senator PROXMIRE. That would mean a fight on the floor, Senator.

INCREASED TRUST FUND REVENUES FROM DAILY TRANSFERS

I just have a few more questions.

Mr. Sabatini, currently, there is a 2-day lag between the time the Social Security Administration issues checks to beneficiaries and the time trust fund moneys are transferred to the Treasury to cover these payments. However, it takes an average of 5.2 days for these checks to clear.

Your Inspector General has recommended a change in Treasury policy under which SSA would transfer trust fund moneys on a daily basis

equal to the value of benefit checks paid out by the Federal Reserve banks for that particular day. Adoption of this policy could result in as much as $91.5 million in additional interest being earned annually by the trust fund.

Are you working with Treasury officials to implement the Inspector General's recommendation?

Mr. SABATINI. We are working with the Treasury Department to find any alternative we can find to increase the interest that is going into the trust fund.

Senator PROXMIRE. Can you keep us up to date and give us information on your progress?

Mr. SABATINI. Yes, sir.

Senator PROXMIRE. Do you think in the next month or so, you would be able to implement this recommendation?

Mr. SABATINI. Well, the recently enacted legislation requires the Secretary of the Treasury and Secretary of HHS to conduct a study—two separate investigations—to identify ways of cutting down the time and maximizing interest in the trust. And we will be working on that, and we will provide it for the record.

Senator PROXMIRE. What I have suggested today is one way to accomplish this objective.

Mr. SABATINI. Yes.

MORE FREQUENT STATE AND LOCAL SOCIAL SECURITY CONTRIBUTIONS

Senator PROXMIRE. The Inspector General also suggested that more frequent deposits of social security contributions by State and local employers on the same schedule as private industry follows could increase trust fund income by $700 million over the next 5 years.

What action do you plan to take to implement an accelerated deposit schedule?

Mr. SABATINI. The national commission recognized that, Senator, and the recently enacted legislation requires that States make their deposits more frequently.

Senator PROXMIRE. So that is being done now?

Mr. SABATINI. Yes.

LAPSED FUNDS IN LIMITATION ON ADMINISTRATIVE EXPENSES

Senator PROXMIRE. Your limitation on administrative expenses seems to include a large amount—$50 million to be exact—which you don't think you'll obligate next year. Based on the historical record, I wonder whether these funds are really necessary.

For example, last year, the appendix to the President's budget indicated no unobligated balance lapsing in 1982. You ended up not spending $58 million.

The appendix to the 1981 budget indicated there would be no unobligated balance lapsing in that year. You ultimately returned $72 million to the Treasury.

If you need these extra administrative funds, we can provide them in a supplemental, but why should we give you this authority to spend now if you don't think you need it, especially in view of the historical record of the last 2 years?

Mr. SABATINI. Well, Senator, the lapsed funds that we have had from year to year—if you look at it in terms of the percentage of the total appropriation—in my opinion is an indication of just good, sound, fiscal management on the part of the administration.

From year to year, the amount of lapsed funds is——

Senator PROXMIRE. But if you don't think you need the funds, why couldn't we just provide them in a supplemental if necessary?

Mr. SABATINI. I think if we can come within 1 or 2 percent of what our total appropriation is, I think that is remarkable.

The fact of the matter is that last year, we came forward and requested a supplemental, but the supplemental was not enacted until sometime in—I think, around September 15.

Senator PROXMIRE. What were your total administrative expenses?

Mr. SABATINI. Total administrative expenses, a little bit more than $3 billion last year. And on September 15, the Congress enacted and gave us a supplemental. September 15, we received a supplemental appropriation from Congress for some $43 million. That gave us approximately 15 days to spend it.

Senator PROXMIRE. Wouldn't it be easier for you to control spending if you had an even tougher limitation?

Mr. SABATINI. I think it would make it more difficult for us to be able to plan and manage the agency if we had those kinds of constraints.

Senator PROXMIRE. Did you have to manage?

Mr. SABATINI. Yes, sir, but——

Senator PROXMIRE. Probably it would affect your state of mind.

Mr. SABATINI. Look at what we faced in 1982 where we went through and had five separate appropriation—four separate appropriation periods and did not know until March 31 what we had available, and then suddenly September 15 we got a supplemental appropriation of some $43 million.

The fact that we were able to manage the fiscal policy of the agency and not spend approximately 2 percent of what we had for the year, I think is something to be proud of.

CONTINGENCY RESERVE

During approximately the last 20 years, Congress has approved a contingency reserve for the Social Security Administration's basic administrative budget account, the limitation on administrative expenses. The reserve enables the Social Security Administration to make a rapid response to increased workloads, or mandatory increases in State agency operational costs, not anticipated in the budget estimates. In fiscal year 1983, for the first time, the contingency can be used for projects to modernize the agency's automatic data processing and telecommunications systems. The contingency reserve is not available unless apportioned by the Office of Management and Budget (OMB) after a demonstration of workload increases and a showing by SSA of maximum absorption of the unanticipated costs. If workloads do not increase and State agency costs do not rise, the contingency may not be used.

As is shown in the following table, a portion of the contingency has been apportioned by OMB to SSA in 4 of the last 5 years. In the last 3 years, the contingency has been apportioned to fund higher payroll costs in the State agencies, to implement provisions of the Social Security Disability Amendments of 1980 and to accelerate debt collection activities. In each of the past 3 years, SSA's unobligated balance was less than the apportioned contingency. The largest unobligated balance occurred last year and in total represented only 1.87 percent of the amount apportioned to SSA, a relatively small amount when one considers the fact that SSA spending is distributed nationally among more than 1,400 offices. Last year's unobligated balance would have been lower if SSA's supplemental request for $114 million had been approved before September 10. All of the supplemental simply could not be used in the time available.

LIMITATION ON ADMINISTRATIVE EXPENSES—BACKGROUND INFORMATION ON CONTINGENCY RESERVE

	Total appropriation[1]	Contingency in appropriation	Contingency apportioned	Total apportioned	Actual obligations	Apportionment less obligations	Percent unused apportionment
Fiscal year:							
1978	$2,120,049,000	$25,000,000	$25,000,000	$2,120,049,000	$2,090,181,013	$29,867,987	1.41
1979	2,257,287,000	25,000,000	.....	2,232,287,000	2,215,555,084	16,731,916	0.75
1980	2,416,999,000	30,000,000	30,000,000	2,416,999,000	2,388,198,000	28,801,000	1.19
1981	2,763,550,000	80,000,000	50,000,000	2,733,550,000	2,690,934,000	42,616,000	1.56
1982[2]	2,982,973,000	70,000,000	70,000,000	2,982,973,000	2,924,744,000	58,229,000	1.87

[1] Figures exclude construction for fiscal years 1978–82.
[2] ADP was apportioned separately in fiscal year 1982 and is excluded from the fiscal year 1982 totals.

STAFFING IN THE LOW-INCOME HOME ENERGY ASSISTANCE PROGRAM

Senator PROXMIRE. You are asking for $2,296,000 for staffing the low-income energy assistance program. Can you tell us how much of your 1982 staffing appropriation remained unobligated at the end of the year, both in dollar terms and as a percentage of your total salaries and expenses budget?

Ms. MCMAHON. I either have it right here or can provide it. $366,000.

Senator PROXMIRE. That is about 10 percent of the total budget, isn't it?

Ms. MCMAHON. That's why we lowered it from $3 million to $2,296,000 from fiscal year 1982 to fiscal year 1984.

Senator PROXMIRE. Now, since 1982, the low-income energy assistance staff has remained at 40 permanent positions. I would think by giving the States greater flexibility and simplifying their administrative requirements, you would be easing your own administrative burden. Why do you continue to need a staff of 40?

Ms. MCMAHON. Actually, we were at 51 work-years in fiscal year 1982. This is not actual live bodies, people sitting down working on the energy program. You have overhead costs and positions, work-years that have to relate to that. So in terms of the actual staff I have working on the energy program, I have 22 people in my central office, and I have 1 person—in a couple of regions 2 people—in the 10 regions across the country.

That is not really a lot of people to deal with almost 200 grantees, although the States have the flexibility to run the programs. And over time, we are trying to get them to do more and more. They still come to us. They still want us to provide program information.

Senator PROXMIRE. Instead of doing more and more, you are doing less and less, and you should need less and less people.

Ms. MCMAHON. We are using less and less people.

Senator PROXMIRE. You still will have 40 positions.

Ms. MCMAHON. As I say, the actual number of people is——

Senator PROXMIRE. Forty positions in 1983, 40 positions in 1984. You are not asking for a reduction.

Ms. MCMAHON. That's right. You get to a level that you can't reduce employees if you are to maintain a staff. And when you are running better than $1 billion program and you have to deal with that number of entities, there is a level of——

Senator PROXMIRE. Then, the greater flexibility and simplification at the State level doesn't mean anything in terms of saving resources for the Federal Government.

Ms. MCMAHON. We have saved resources. We have gone from $3 to $2 million.

Senator PROXMIRE. You are not continuing to save the resources in 1984.

Ms. MCMAHON. If you are asking me——

Senator PROXMIRE. This simplification and streamlining is supposed to take place in 1984, is it not?

This is when you should be reducing your personnel.

Ms. McMAHON. We have already done that. We have implemented the bulk of changes in relation to the Federal role.

Senator PROXMIRE. Thank you, Mr. Chairman.

EXPERIENCE UNDER THE NEW VOCATIONAL REHABILITATION PROGRAM

Senator WEICKER. The Omnibus Budget Reconciliation Act of 1981 permits use of supplemental security income funds to reimburse vocational rehabilitation agencies only for services given to disabled SSI recipients who, thereafter, succeed in performing substantial gainful activity for a continuous period of 9 months.

How sharply have States cut back efforts to rehabilitate disabled supplemental security income recipients in view of the new law limiting reimbursement from SSI funds to successful cases?

Mr. SABATINI. Senator, we haven't had that much experience to be able to answer that and give you any detailed numbers.

The intent of that legislation, of course, was to make both the trust fund and the SSI rehabilitation program more realistic in terms of their relationship to basic programs. There is a basic vocational rehabilitation program that is designed to provide rehabilitation services to this population.

That program itself requires that services be targeted to the severely disabled. And, of course, these are the people we are talking about.

The intent of the change was to utilize the money from the trust funds and from the SSI appropriation to specifically allow us to address that money to provide those kinds of services that will return people to gainful employment.

Senator WEICKER. How many disabled SSI recipients received rehabilitation services in fiscal 1981 and fiscal 1982?

Mr. SABATINI. Well, I don't have that. We can get it; we can submit that.

Senator WEICKER. Do you have a forecast for 1983 or 1984, or would you prefer to answer this entire series for the record?

Mr. SABATINI. My preference would be to answer it for the record.

PREPARED STATEMENT AND QUESTIONS

Senator WEICKER. We will include your statements in the record at this point along with further questions.

[The information follows:]

STATEMENT OF NELSON SABATINI

Fiscal Year 1984 Appropriation Requests

Mr. Chairman and members of the Committee, I am pleased to be with you today to present the fiscal year 1984 budget requests for the Social Security Administration, the Office of Child Support Enforcement and the Office of Refugee Resettlement. These requests total $22.8 billion in budget authority, a decrease of $2.6 billion from fiscal year 1983.

Summary of Budget Requests before the Committee

I would like to summarize for you the fiscal year 1984 requests before your Committee that require appropriations action. These appropriation requests do not reflect the impact of the Social Security Amendments of 1983 recently passed by the Congress. We are currently evaluating the effect of this legislation on our appropriation requests and will be amending our estimates as appropriate.

--$838.6 million for Payments to Social Security Trust Funds. Through this account the trust funds are reimbursed for the costs of certain benefits and administrative expenses chargeable to Federal funds.

--$1.0 billion for Special Benefits for Disabled Coal Miners. These funds cover benefit payments and administrative expenses for that portion of the black lung program still administered by SSA.

--$7.9 billion for the Supplemental Security Income Program. This request includes SSI benefits and reimbursement to the Social Security trust funds for the administrative costs of the SSI program.

--$7.1 billion for the Assistance Payments Program. This appropriation includes the Federal share of the benefit costs of the Aid to Families with Dependent Children program and funds for Federal policy direction, technical assistance and guidance in the administration of the AFDC program. Child

Support Enforcement collections are included in this account as an offset to AFDC benefit payments.

--$416.5 million for the Child Support Enforcement Program. This appropriation provides funds for Federal, State and local administration of the program, the aim of which is to assure that absent parents meet their responsibilities to provide support for their children.

--$1.3 billion for Low Income Home Energy Assistance. This provides funds for grants to States and Indian tribes for energy assistance to low income households. Federal administrative costs for these programs are included in the appropriation request.

--$485.3 million for Refugee and Entrant Assistance. The Refugee Assistance program reimburses States for the costs of providing direct cash and medical assistance for needy refugees as well as English language training, vocational training and other social services, for the purpose of assimilating refugees into American society as quickly and effectively as possible. The Cuban-Haitian Entrant program reimburses States for the cost of assistance provided to certain Cuban and Haitian arrivals in the United States. Entrant assistance is comparable to that provided to refugees, and it is based on the provisions of title V of the Refugee Education Assistance Act of 1980.

--$3.7 billion for the Limitation on Administrative Expenses. This request provides the funds needed to administer the old-age and survivors and disability insurance trust fund programs. It also includes funds to cover certain administrative costs of the Medicare program and administrative funds for the Supplemental Security Income Program, and several smaller programs. The trust funds are reimbursed for the administrative costs of the SSI and other nontrust fund programs through appropriations to other accounts.

Social Security Financing

Congress recently passed legislation to put the Social Security system back on sound financial footing. This legislation will affect primarily the financing of Social Security benefits. Funds to pay benefits from the Old-Age and Survivors Insurance and Disability Insurance Trust Funds are permanently appropriated, and therefore are not part of the budget requests before this Committee. However, the legislation also will affect three appropriated accounts that I will be discussing today. These accounts are: Payments to the Social Security Trust Funds, Supplemental Security Income, and the Limitation on Administrative Expenses. The Administration soon will be sending requests to the Committees related to changes in budget requirements resulting from the new legislation.

Reasons for Decreases from FY 1983 Estimates

There are four principal reasons for the decrease of $2.6 billion in the total fiscal year 1984 request from the fiscal year 1983 level:

1. The SSI program estimate for fiscal year 1983 is based on 13 months of benefit payments while fiscal year 1984 includes only 11 months of benefit payments. This occurs as the result of legislation which requires early mailing of SSI checks when the first day of the month falls on a weekend. October 1, 1983, the first day of FY 1984, falls on a weekend, so the October 1983 checks must be mailed in September 1983 (in fiscal year 1983).

2. The effect of proposed legislation in the Assistance Payments and Child Support Enforcement programs in fiscal year 1984 is to decrease AFDC benefit payments and increase child support collections.

3. Of the fiscal year 1983 funds appropriated for the Assistance Payments program, $632 million was used to fund the fiscal year 1982 shortfall. In contrast, the fiscal year 1984 appropriation includes $35 million for the anticipated fiscal year 1983 shortfall.

4. The estimate for the Low Income Home Energy Assistance program is reduced in fiscal year 1984 compared with fiscal year 1983 because the $1.3 billion included for the program in fiscal year 1984 will be adequate with appropriate targeting of assistance by the States to those who truly need help.

Agency Initiatives

Now I would like to report briefly on two of the Agency's most important initiatives:

--Systems Modernization: On March 2, 1982 the Agency's Systems Modernization Plan was announced. The plan is designed to replace SSA's outdated system of hardware, software and storage capacity with one that is modern, efficient and reliable. The Administration's budget request for fiscal year 1984, like those for fiscal years 1982 and 1983, provides full funding for this plan. We appreciate the support that the Committee has provided for full funding of SSA's systems modernization efforts and its approval of no-year appropriations language for automatic data processing and telecommunications expenses in fiscal years 1982 and 1983. SSA is requesting similar language in fiscal year 1984.

SSA is now well into the first 18 month "survival" period described in its Systems Modernization Plan. We have made one report to the Committees about our progress and will make further periodic reports. Some of our recent accomplishments include:

1. Award of a Systems Engineering and Integration contract to provide continuous private sector management and technical engineering support to the plan until all aspects of the program are completed.

2. Continued enhancement of the Social Security Administration Data Acquisition and Response System--SSADARS--SSA's telecommunications network which links the Agency's field offices with the central computer

facility. Two modern large scale processors were installed in February to replace the overloaded processors. High speed communication line upgrades for the network were completed in January 1983. Functional specifications for engineering the new data communications utility have been completed, and a request for proposals is being prepared to acquire the necessary software, hardware and communications.

3. Completion of a large-scale disk purchase to enable us to begin converting SSA's sequential tape files to direct access storage.

4. Initiation of the Requirements Analysis project which provides for a comprehensive review of our functional requirements for developing new systems for SSA's programs.

5. Improvement of existing software for the OASDI program and initiation of the design of a new annual wage reporting system.

--Disability Program Improvements: SSA is implementing a series of initiatives to improve administration of the disability programs, primarily to address problems that developed in implementing the legislative mandate to review periodically the continuing eligibility of disability beneficiaries.

1. Beginning October 1982, at the front end of the process each beneficiary scheduled for a continuing disability investigation receives a face-to-face interview by SSA personnel in a district or branch office. This personal contact before the investigation begins avoids further review of cases where termination obviously is not warranted. Also it provides beneficiaries with a better explanation of the continuing disability investigation process and their rights and responsibilities.

2. SSA is improving disability case processing in its local offices through revised training, improved communications between SSA field offices and State Disability Determination Services, and improved instructions and forms used by SSA and State offices.

3. For FY 1984, we have requested funds to replace the existing paper reconsideration process, which is the first step in the appellate process, with a face-to-face evidentiary hearing in continuing disability investigation termination cases. This change was mandated by P.L. 97-455, signed by the President on January 12, 1983.

4. Beneficiaries now can elect to have benefits continued during the appeals process up through the level of a hearing by an Administrative Law Judge, in cases of disability cessation. This change in procedure also was authorized by P.L. 97-455.

Payments to Social Security Trust Funds

The first appropriation request totals $838,583,000 and covers three Federal fund payments to the Social Security trust funds.

Military Service Credits

Our appropriation request does not reflect the impact of the Social Security Amendments of 1983, recently passed by Congress. We are currently evaluating the effect of this legislation, and we will be amending our request shortly. However, given this Committee's continuing interest in and support of the Social Security program, we want to bring to your attention a provision of the legislation which significantly affects this request in FY 1984.

The provision affects the first of three activities in this account, that of Military Service Credits which reimburses the Old-Age and Survivors Insurance and Disability Insurance Trust Funds for the costs of benefits paid as a result of granting noncontributory credits for military service. The request before this Committee for military service credits is $713,325,000. The new legislation provides for a lump-sum transfer in FY 1983 to the Old-Age and Survivors Insurance and Disability Insurance Trust Funds for the present value of future benefits arising from pre-1957 military service wage credits and the

for the same period. Under the new legislation, the trust funds will be reimbursed on a current basis for such employer-employee taxes on credits for military service after 1983. This legislation will reduce the FY 1984 request for reimbursement for pre-1957 wage credits to zero and will increase the FY 1984 request for post-1956 credits.

We will be reviewing the legislation to determine if any other of its provisions will affect this account.

Special Payments to Certain Uninsured Persons

The second activity in this account is for payment of $124,514,000 to reimburse the Old-Age and Survivors Insurance Trust Fund for special benefits paid during FY 1982 to certain uninsured persons aged 72 years and over. The payments are made to individuals who did not have a chance to work long enough under Social Security to become insured. These persons, a declining population, were not eligible for regular monthly Social Security benefits primarily because they retired before enactment of the Social Security Act or before their occupations were covered under Social Security.

The special payments to certain uninsured persons decreases $14,148,000 from FY 1983. The population receiving special payments is a closed group of very aged persons which grows smaller each year. As of September 30, 1982, 66,000 persons were receiving benefits chargeable to the general funds under this provision as compared to 80,000 a year earlier.

Reimbursement for Pension Reform Administrative Costs

The third activity is for payment of $744,000 to reimburse the Old-Age and Survivors Insurance Trust Fund for the Federal funds share of the cost of administering pension reform responsibilities assigned to the Social Security Administration under Public Law 93-406, the Pension Reform Act. The reimbursement is for the cost of furnishing information on deferred vested pension rights to pension plan participants or their survivors. The FY 1984

estimate for pension reform administrative costs reflects a continuation of SSA's FY 1983 pension reform activities.

Special Benefits for Disabled Coal Miners

This appropriation request for Special Benefits for Disabled Coal Miners totals $1,027,047,000 and is financed from general revenues. It includes $1,018,000,000 for benefit payments and $9,047,000 for administrative costs. It does not include reimbursable work done for the Department of Labor, which is budgeted for by that Agency.

Program Authorization

The black lung program is authorized by title IV of the Federal Mine Safety and Health Act of 1977, which provides for payment of monthly cash benefits to coal miners who are totally disabled because of pneumoconiosis, commonly referred to as black lung disease, and to widows of miners who were entitled to these benefits or whose deaths were due to this disease. Payments to miners or widows are increased for dependents--a spouse or child. Benefits also are payable to surviving children of miners and, in certain circumstances, to totally dependent surviving parents, brothers and sisters.

Responsibility for Administration

The Social Security Administration is responsible for processing and paying claims for miners' benefits filed from December 30, 1969 through June 30, 1973 and claims for survivor benefits filed through December 31, 1973 or within 6 months after the death of a miner or widow already on the beneficiary rolls maintained by SSA. SSA must continue to pay benefits and maintain the beneficiary rolls for the lifetime of all persons who filed with SSA during its jurisdiction.

Since June 30, 1973 SSA has continued to take miners' claims--but as an agent of the Department of Labor, which is responsible for adjudication and payment of these claims and thus budgets to reimburse SSA for this work.

The beneficiary rolls for which SSA has responsibility will continue to decline gradually in years to come. At the mid-point of FY 1984, 329,000 miners, widows and dependents will be receiving monthly benefits paid by the Social Security Administration from this appropriation. This is a decrease of 21,000 from the 350,000 beneficiaries who will be receiving payments at the mid-point of FY 1983.

Supplemental Security Income

The Supplemental Security Income (SSI) appropriation provides funds through direct cash assistance to eligible aged, blind and disabled recipients to help finance their basic needs. The appropriation request for FY 1984 is $7,851,518,000. This includes $6,913,000,000 for Federal benefits to aged, blind and disabled recipients; $5,000,000 for hold harmless payments; $4,601,000 for beneficiary rehabilitation services; $899,976,000 for payments to the trust funds for administrative costs and $3,900,000 for administrative costs for SSI disability demonstration projects; and $25,041,000 for reimbursing States for incorrect State supplementary payments made as a result of Federal errors. The appropriation request for FY 1984 reflects a projected cost of $341,000,000 from new legislation. We are currently evaluating and will be revising these estimates in light of the Social Security Amendments of 1983.

Federal Benefit Payments

The SSI program ensures a minimum monthly level of income to eligible aged, blind and disabled individuals. An individual's income, resources and living arrangements are evaluated to determine the actual amount of SSI payment. Payments are delivered through monthly benefit checks.

Explanation of Change from FY 1983 Request

We expect benefit payment obligations to be $1,018,000,000 in FY 1984--$57,000,000 less than in FY 1983. Because the budget assumes a

freeze on Federal pay, and the basic black lung benefit is tied to Federal pay scales, that amount is also frozen. The decrease in total benefits is due to a reduction of $54,000,000 for the decreasing number of black lung beneficiaries, and $3,000,000 because the number of black lung claims with retroactive payments is dropping off as cases under appeal are settled.

Our budget request of $9,047,000 for FY 1984 black lung administrative expenses is $1,953,000 lower than the level estimated for FY 1983. This is caused in part by a reduction in ongoing workloads. It also results from the expected completion during FY 1983 of corrective efforts undertaken to improve the integrity of the black lung benefit roll.

The FY 1984 request for Federal benefit payments, prior to consideration of the Social Security Amendments of 1983, is $6,913,000,000 or $867,486,000 lower than the FY 1983 level. The major cause of this year-to-year decrease is the October 1, 1983 payment which will total $620,000,000. Since October 1st falls on a Saturday when banks are closed, the payment will, by law, have to be made on September 30, 1983, which is in FY 1983 rather than in FY 1984. The result is that FY 1983 will include payments for 13 months and FY 1984 will only include 11 payments. However, after adjusting for the difference in the number of payments, the FY 1984 request actually represents a comparable increase of $372,514,000 for Federal benefit payments.

This net increase would be higher except for the following factors:

--SSA's initiatives to improve payment accuracy by locating and terminating ineligible recipients and correcting payments to eligible recipients. A number of initiatives are in place or planned to improve the quality of disability determinations, to insure stricter development, to identify error prone cases and to verify entitlement through special validations against records of other Federal and State programs.

--Increases in Social Security benefits due to cost-of-living adjustments reduce average SSI payments. Roughly half of the SSI recipient population

also receive title II benefit payments, and their SSI benefits must be reduced as their income from other sources increases.

--A new initiative to identify the bank accounts of SSI applicants and beneficiaries by an automated procedure with IRS. This procedure will assure that resources in these bank accounts are considered in determining the eligibility of SSI recipients and in determining their appropriate benefit payment.

Hold Harmless Payments to States

The hold harmless provision, included in the original SSI legislation (P.L. 92-603), provided for the Federal Government to assume liability for certain State supplementation payments made to raise the total assistance up to the level received by the recipients prior to the SSI program. This provision was intended as a means of limiting a State's supplementary payment costs in the event that large numbers of new recipients were brought on to the rolls by the transition to SSI. All States but three (Wisconsin, Massachusetts and Hawaii) lost their eligibility for this program because their costs for supplementary payments subject to hold harmless protection diminished as a result of the rising Federal benefit level. However, in 1975 an amendment (P.L. 94-585) to the original legislation provided for disregarding increases in Federal SSI payments in computing payments protected by the hold harmless provision. By this means a transitional program was turned into an open-ended one for a few States.

In FY 1984 the Administration will continue the phase-out of hold harmless payments. The Tax Equity and Fiscal Responsibility Act of 1982 (P.L. 97-248) contained a provision that continued this phase-out which was begun in FY 1982 by means of a funding limitation contained in the SSI appropriation language. The phase-out was based on 60 percent of costs in FY 1982, 40 percent of such costs in FY 1983, 20 percent in FY 1984 and the complete phase-out of the program in FY 1985. We anticipate that two States will still

qualify for this program in FY 1983 and FY 1984--Wisconsin and Hawaii. Of the total appropriation request in FY 1984, 99.8 percent is for Wisconsin.

Beneficiary Rehabilitation Services

As a result of the Omnibus Budget Reconciliation Act of 1981, SSA will provide funds only to reimburse vocational rehabilitation agencies for costs incurred in successfully rehabilitating SSI recipients. It is anticipated that State vocational rehabilitation agencies will take on fewer difficult cases because of the revised definition of success and the likelihood that reimbursement will be less certain. Based on this change in law, we estimate that $3,000,000 will be required for vocational rehabilitation in FY 1984. In addition, we are requesting $1,601,000 for the referral and monitoring of SSI recipients who are drug addicts and alcoholics.

Administrative Costs

Payments to the Trust Funds for Administrative Costs:

The SSI and Social Security programs are administered on an integrated basis for purposes of economy and efficiency. The Social Security Act authorizes advances from the Social Security trust funds to pay the administrative costs of the SSI program through the Limitation on Administrative Expenses. The advances are fully repaid from the SSI appropriation. SSA maintains a detailed cost allocation system which has been audited by the General Accounting Office to ensure that the trust funds are made whole (with interest, if appropriate) for the administrative expenses of the SSI program. The FY 1984 request for this activity is $899,976,000. We will be amending the request for SSI administrative expenses to reflect the cost of implementing the SSI program changes included as part of the Social Security Amendments of 1983.

Demonstration Projects:

The Social Security Disability Amendments of 1980 (P.L. 96-265) authorize waiver of certain provisions of the Social Security Act in order to conduct demonstration projects likely to assist in promoting the objectives or facilitating the administration of the SSI program. The demonstration projects being considered would, for example, provide the information needed to properly evaluate current alcoholic and drug addiction programs in order to determine the best approach in preventing the onset of irreversible medical conditions and restoring the addicts' capacity to work. They also would demonstrate whether mentally retarded recipients can make a transition to work through support from various services which would be reduced as the individuals gain self-confidence and ability. The major objective of these demonstration projects is to find ways to use scarce program and administrative dollars more effectively. We are requesting $3,900,000 in order to carry out such demonstration projects in FY 1984.

Federal Fiscal Liability

The Social Security Administration administers supplemental payments for 26 States and the District of Columbia. Agreements with the States governing Federal administration of these State supplementary payments provide for Federal fiscal liability (FFL) for payment errors in excess of a 4 percent tolerance.

SSA's FFL estimates are largely dependent on two factors: FFL error rates and the resolution of negotiations with the States over disputed periods. This budget assumes that in FY 1984 all outstanding FFL through September 1983 will be settled. We are requesting $25,041,000 for this activity in FY 1984.

Assistance Payments

This appropriation finances the Assistance Payments program which provides funds through grants to States and local governments for diverse activities

related to public assistance to the needy. Although the Social Security Administration is responsible for the programs covered by this appropriation, no trust fund money is used for assistance payments purposes. For fiscal year 1984 the Assistance Payments request, which includes $722,000,000 in assumed savings from proposed legislation, is $7,129,784,000. The total appropriation for FY 1984 is the sum of the regular appropriation requested at this time ($5,411,784,000) and the advance appropriation for the first quarter of FY 1984 previously enacted ($1,718,000,000). The total request includes $7.06 billion for maintenance assistance, which includes Aid to Families with Dependent Children and related programs; $2.58 million for research and evaluation; $34.9 million for Federal administrative expenses; and $35.4 million to replace funds borrowed from fiscal year 1984 to cover the anticipated funding shortfall in fiscal year 1983.

At this time, we are also requesting an advance appropriation of $1,758,454,000, which includes assumed savings from proposed legislation, to fund first quarter FY 1985 grants. This advance appropriation is the mechanism, which replaced "borrowing" authority, for providing funds in the current year for issuing first quarter advance grants for the next fiscal year. The mechanism protects the States from gaps in funding and enables them to plan in advance for first quarter operations.

Before we get into the reasons for the year-to-year change in our appropriation request, I'd like to make two general points:

--The FY 1984 appropriation request is about $1.2 billion less than the FY 1983 appropriation.
--When adjustments are made for amounts in the FY 1983 appropriation used for the FY 1982 shortfall ($.5 billion) and proposed legislation included in the FY 1984 estimates ($.7 billion) the FY 1984 request is approximately the same as our FY 1983 estimate.

The following portions of this statement address in more detail the FY 1984 request, including the impact of legislation proposed for enactment in

FY 1984, for the Maintenance Assistance, Research and Evaluation, and Federal Administration activities and for funding of the FY 1983 shortfall.

Maintenance Assistance

The fiscal year 1984 request for the Federal share for the maintenance assistance activities is $7,056,885,000. The request includes:

--$5,865,000,000 for Aid to Families with Dependent Children (including a reduction for offsetting child support collections of $425,000,000).

--$13,875,000 for assistance to aged, blind and disabled adults in Puerto Rico, Guam and the Virgin Islands; the Supplemental Security Income program does not cover these jurisdictions.

--$52,500,000 for emergency assistance to needy families with dependent children.

--$1,116,378,000 for State and local administrative costs related to the maintenance assistance programs.

--$7,722,000 for administration and training costs in Puerto Rico, Guam and the Virgin Islands.

--$1,410,000 for assistance to repatriated U.S. Nationals returning from foreign countries who have been certified by the Department of State as destitute or ill.

The FY 1984 request for these maintenance assistance activities is $673,753,000 lower than the FY 1983 level for the same activities. This decrease is the net result of several factors of decrease and increase primarily in the AFDC and State and local administration and training costs activities. Significant decreases in the Federal share of program costs result from the following factors:

--A decrease of $722 million from the FY 1983 level as a result of savings from legislation proposed for enactment in FY 1984 which would strengthen AFDC work requirements and target AFDC benefits more fairly.

--Savings of $27 million resulting from a projected reduction in States' payment error rates from 5.7 percent in FY 1983 to 5.3 percent in FY 1984.

--Additional savings of $60 million in FY 1984 through imposition of fiscal sanctions based on projection of error rates which exceed the mandated error rate targets in the FY 1982 and FY 1983 reporting periods. The budget estimate of the sanction amounts is based on national average error rate trends, not on projections of specific State error rates.

--Increased savings of $25 million in Child Support Enforcement collections resulting from increases in the caseload and the average collection per case and from provisions in the Tax Equity and Fiscal Responsibility Act of 1982 which increase the Federal share of collections.

Significant increases in AFDC and State and local administration and training, are:

--AFDC increases $155 million resulting from economic and demographic factors including: an increase in average benefits, due to both inflation and increases in State standards of need; an increase in the number of families headed by females, the major source for the AFDC caseload; and an offsetting decrease in the unemployment rate.

--State and local administration and training increases $59 million resulting primarily from the projected increase in prices and wages.

Research and Evaluation

We are requesting $2,575,000 for research and evaluation grants and contracts under sections 1110 and 1115 of the Social Security Act, a reduction of

$375,000 over the FY 1983 level. The aim of these projects is to improve the management of the AFDC program and to assess policies which promote work experience for recipients and thus reduce welfare dependency. Some of the projects planned include demonstration of techniques to improve the effectiveness of Community Work Experience programs, evaluation of grant diversion and demonstration of fraud and error reduction methods. Although most of the money is for research and demonstration projects related to the AFDC program, some of the funds are used for Social Security and SSI extramural research grants and contracts.

Federal Administrative Expenses

The FY 1984 request includes $34,946,000, an increase of $2,446,000 over the FY 1983 level, and 757 full-time permanent positions, the same number as in FY 1983. The increase of $2,446,000 is necessary to cover mandatory costs such as the costs of the full-year effect of the October 1982 pay raise, within-grade raises and promotions, rent, and utilities. The FY 1984 request provides the resources necessary to continue the efforts, at the FY 1983 level, to implement and evaluate the provisions of Omnibus Budget Reconciliation Act of 1981 and the Tax Equity and Fiscal Responsibility Act of 1982.

Funding of FY 1983 Shortfall

The FY 1984 request includes $35,378,000 to replace funds borrowed from FY 1984 to cover a funding shortfall in FY 1983. The shortfall in FY 1983 results primarily from changes in demographic and economic conditions since the enactment of the FY 1983 appropriation. On an activity basis, the FY 1983 appropriation is less than the revised estimate for FY 1983 by $146,699,000. However, funds to cover $111,321,000 of this shortfall are available in FY 1983 from the following sources:

--$14,140,000 in unobligated balances carried over from FY 1982 for use in FY 1983.

--$96,681,000 from funds provided in the FY 1983 appropriation for the anticipated FY 1982 shortfall, but not needed for that purpose in FY 1982.

--A transfer of $500,000 from the FY 1983 Refugee and Entrant Assistance appropriation to fund the October 1982 civilian pay raise.

As previously mentioned, the remaining shortfall of $35,378,000 will be funded from funds requested in the FY 1984 appropriation for that purpose.

Funding Food Stamps Eligibility Certification

Lastly we would like to bring to the Committee's attention a change in the way we will be budgeting to fund food stamp eligiblity certifications for AFDC applicants and recipients. In April 1982, the Department of Health and Human Services promulgated a regulation which requires States to change the way they charge the Federal Government for its share of the cost of determining whether AFDC recipients are eligible to receive Food Stamps. In the past, all of these costs have been charged to this appropriation. Although we have budgeted once again for all of these costs in this appropriation, we are working with the Department of Agriculture to determine the magnitude of funds involved so that appropriate transfers from this appropriation may be made to them. Our General Counsel has told us that this approach is more consistent with the recently promulgated regulations.

Low Income Home Energy Assistance

The Low Income Home Energy Assistance Program (LIHEAP) appropriation provides funds through grants to States and Indian tribes to enable them to provide assistance to low income households in meeting the high costs of home energy. The FY 1984 budget request is for $1.3 billion for this purpose. This includes $1,297,704,000 for grants to States and Indian tribes and $2,296,000 for Federal administrative expenses. The appropriation language reflects a substantive change which will allow alteration of the formula to

allocate funds among the States so as to target funds to those States with the greatest need. Legislation also is being submitted to the authorizing committees.

Program Grants

We are requesting $1,297,704,000 to provide grants to States and Indian tribes to aid low income families through payments to eligible households, energy suppliers and building operators. This assistance is primarily for heating but may be used for cooling costs or low-cost weatherization.

The FY 1984 request represents a decrease of $686,007,000 from the amount for this program in FY 1983. This budget proposal must be viewed in the context of the purpose of the Energy Assistance program and the entire Federal budget. When viewed in this context, the fact that the Administration is proposing a substantial level of funding for this program--over $1 billion--at a time when we need to reduce Federal spending, demonstrates our commitment to providing help with energy costs to the truly needy.

It is important to bear in mind that the Energy Assistance program was never intended to pay the entire energy bill for all low-income households. Rather, this program is designed to supplement all the other Federal, State and other programs which provide needy households with assistance in obtaining "the basics"--housing, food, medical care, home energy, etc. The Energy Assistance program exists to ensure that households which need additional help with energy costs, notwithstanding all the other basic needs assistance available from other programs, can get help. We believe that if we, at the Federal level, and the States, appropriately target assistance to the most needy, $1.3 billion of energy assistance funding is adequate to ensure that this goal is met.

Federal Administration

The FY 1984 request includes $2,296,000 for funds to enable the Social Security Administration to administer the energy block grant for States and Indian tribes. These activities include reviewing State plans, issuing grants, financial tracking and accounting, compliance and monitoring reviews, and preparing the annual report to Congress. The $2,296,000 request represents an increase of $7,000 over the FY 1983 level to cover the cost of the full-year effects of the October 1982 payraise, the 1.3 percent Medicare tax, and costs of promotions, within-grades and other mandatory increases.

Limitation on Administrative Expenses

The Limitation on Administrative Expenses is a request for authority to spend up to $3,723,317,000 from the trust funds for most of the fiscal year 1984 administrative expenses of the Social Security Administration. This request does not reflect the effect of implementing the Social Security Amendments of 1983 recently passed by Congress. We are evaluating the impact of the new legislation and will be amending our request as appropriate. Changes in administrative budget requirements resulting from this legislation will be submitted soon to the Appropriations Committees.

From this account we pay for administration of the old-age and survivors and disability insurance programs, Medicare work performed by SSA, and the construction needs of the Social Security trust fund programs. In addition, because for reasons of economy and efficiency SSA has integrated administration of both trust fund and some nontrust fund programs, the law authorizes payment of nontrust fund administrative expenses from this account, with full reimbursement from general funds. The nontrust fund work handled in this way includes work relating to the Supplemental Security Income Program, work associated with the Pension Reform Act of 1974, and the portion of annual wage reporting work done by SSA for the benefit of the Internal Revenue Service.

Of the new budget authority requested:

--$1.3 billion is for administering the old-age and survivors insurance program,

--$1.2 billion is for the disability insurance program,

--$131.1 million is for SSA's Medicare support functions,

--$900 million is for administering the SSI program,

--$74.1 million is for processing annual reports of earnings,

--$0.7 million is for pension reform responsibilities,

--Included in these program costs is an estimated $200.1 million for automated data processing and telecommunications activities,

--Another $44.4 million is for SSA's construction needs, and

--$50.0 million is for the contingency reserve, which provides funds to SSA only if workloads, automation projects and certain specified costs exceed the budget estimates.

Budget Emphases for FY 1983 and FY 1984

SSA's administrative budget request reflects three general areas of emphasis in fiscal years 1983 and 1984.

I've already discussed two in my general opening statement. I'll just touch on them briefly.

1. Systems Modernization

The FY 1984 systems request is $200.1 million, an increase of about $30 million over the FY 1983 comparable level. This amount will fund SSA's continuing progress towards modernizing its systems hardware and software as well as the Agency's ongoing systems costs. Included in the FY 1984 request is a proposal to include $19.8 million for major telephone procurements as a part of the no-year ADP funding. For fiscal years 1982 and 1983 Congress approved special appropriations language which provides extended availability of ADP and telecommunications funds.

2. Disability Program Administration

In this area, SSA has launched a program of initiatives:

--to control the growing caseload of pending hearings cases, SSA is asking for 6,445 work-years and $227.4 million in FY 1984 for the Office of Hearings and Appeals, and

--to address the concerns arising from the continuing disability investigations mandated by the Disability Amendments of 1980, there is $44.4 million and 1,693 work-years in this budget for the plan to improve the disability and appellate processes.

3. Debt Collection

SSA will continue to emphasize detection and resolution of debt. In FY 1984, we will spend 5,776 work-years and an estimated $143.8 million in this account for debt collection work. As a result of SSA's efforts, collections from all programs rose from $635 million in FY 1981 to almost $1 billion in FY 1982. Improved debt collection is designed to raise the public's confidence in the quality of program administration and in the Government's effectiveness in safeguarding trust fund assets. At the same time, in fairness to the beneficiary, SSA will continue to recognize the overpaid individual's rights to due process including waiver when statutory requirements are met, and will strive to negotiate reasonable installments and compromise settlements.

Workloads

SSA has a workload-based administrative budget, the size of which is determined to a great extent by workloads generated by provisions of the law and demographic factors. Some examples of principal workloads for FY 1984 are to:

--process over 3.8 million claims from retired workers, dependents and survivors; nearly 1.5 million claims from disabled workers, dependents and survivors; and about 1.0 million SSI claims.

--keep the beneficiary rolls current for 36.5 million persons under the Social Security cash benefit programs and for 3.7 million SSI recipients.

--complete 3.5 million redeterminations for SSI eligibility and payment amount.

--process more than .5 million hearings from claimants who are appealing decisions concerning their eligibility and benefits, primarily in the disability and SSI programs.

--post 211 million annual wage report items.

Work-Years and Positions

For this appropriation, SSA is requesting 85,346 work-years for FY 1984, a decrease of about 1,800 work-years from FY 1983. This work-year decrease results primarily from:

1. The implementation of procedural and systems improvements such as:

   o automating billing and remittance processes,
   o combining the SSA-retirement claims application and computer input forms and, thereby, reducing manual processing, and
   o continuing enhancement of the SSA data acquisition and response system (SSADARS) which links SSA field offices with the central computer facility.

2. Completion of non-recurring work in FY 1983. The FY 1984 request assumes that SSA will:

- o eliminate backlogs in its debt collection work in FY 1983,
- o have behind it the FY 1983 start-up and implementation of provisions of the Tax Equity and Fiscal Responsibility Act of FY 1982, and
- o complete the final phase of the move to the New Computer Center in 1983.

The situation in full-time permanent positions is quite different than the picture in work-years. For the Limitation account we are asking for 78,029 full-time permanent authorized positions in FY 1984. This is about 1,700 positions higher than the FY 1983 level, which itself is about 200 positions higher than the request presented to Congress last Spring. We are requesting an increase in the number of full-time permanent positions authorized in fiscal years 1983 and 1984 for the following reasons:

1. Within the Executive Branch today there is a new system for counting the various categories of Federal employment that is consonant with the Federal Employees Part-time Career Employment Act of 1978. Under this system certain employees who formerly were not counted as full-time permanent are now counted in this category because they have permanent appointments. For SSA this change in counting methodology is significant. Because of the large seasonal workforce we employ for annual wage reporting, about 1,600 seasonal and other employees now fall in the full-time permanent category.

2. The local managers of SSA offices believe that they can do a more efficient job if they can avail themselves of the flexibility offered by the new full-time equivalent (FTE) system of managing employment that has been adopted within the Executive Branch. Under this system the employment count is based on cumulative work hours used throughout the fiscal year rather than on the number of employees on duty at a given point in time. If the Committee agrees to let us raise the number of full-time permanent authorized positions, we have the flexibility to meet our FTE ceilings by increasing full-time permanent employment, while decreasing part-time and temporary employment.

Finally, SSA's request for the Limitation account includes an increase in overtime work-years--from 3,664 in the FY 1983 budget to 4,279 in FY 1984. The more we meet our work-year requirements through overtime, the less need there is to hire additional Federal employees.

Disability State Agencies

The FY 1984 budget request includes $698,000,000 for the State agencies, about 19 percent of our administrative budget. The disability State agencies have required an increasing share of our administrative budget because:

--the requirements of the Disability Amendments of 1980 increased State agency administrative costs by more than $14,291,000 over FY 1983 costs for these procedures. This legislation provides for a Federal review of State agency determinations in Social Security disability cases before the award is made, periodic review of current disability beneficiaries, personalized denial notices, and purchase of medical evidence for Social Security cases.

--the rate and cost of consultative examination purchases increased. The consultative examination rate has increased from 30.3 percent in FY 1978 to an estimated 41 percent in FY 1984.

STATEMENT OF FRED SCHUTZMAN

The Child Support Enforcement appropriation provides funds through grants to States to enable them to assist families by locating absent parents, establishing paternity, obtaining child support orders and enforcing the support obligations owed by absent parents to their children. The aim of the program is to help families to maintain their financial independence and to stay off public assistance by assuring that absent parents meet their responsibility to support their children. The FY 1984 budget request is for $298,463,000 including $10,000,000 savings from proposed legislation. This is in addition to the $118,000,000 which Congress provided as an advance appropriation to fund first quarter State and local administrative grants. Therefore, the total FY 1984 appropriation is $416,463,000. This includes

$393,813,000 for the Federal share of State and local administrative costs, $22,200,000 for Federal administrative expenses and $450,000 for research and evaluation.

At this time we also are requesting an advance appropriation of $102,750,000 to fund first quarter FY 1985 grants. The advance appropriation will provide funds in FY 1984 for issuing first quarter advance grants for the first quarter of FY 1985. Such a procedure enables States to continue program operations without interruption and to plan in advance.

The appropriation request for FY 1984 reflects projected savings of $10 million from legislation proposed for enactment in FY 1984. The proposed reforms are being transmitted concurrently to legislative committees of Congress. The reforms address concerns expressed by this Committee that the Child Support program needs to improve its efficiency and fiscal posture. The proposed reforms will strengthen the Child Support program by relating program financing more directly to performance, stimulating increased collections and improving cost effectiveness. The changes will be phased in gradually to facilitate the States' transition to the new financing structure. Thus, the savings from this proposal will grow substantially over the next few years. The request for the FY 1985 advance appropriation reflects first quarter savings of $12,750,000 from these legislative proposals. In addition, legislation intended to produce increased child support collections is included in the Assistance Payments appropriation. The proposal would require States to include in their State plans certain techniques which have proven to be effective, including mandatory wage assignment when payments are delinquent, State income tax refund offsets for delinquent payments, and use of quasi-judicial and administrative procedures to establish and enforce obligations.

State and Local Administrative Costs

The FY 1984 request for the Federal share of State and local administrative grants, $393,813,000, is $19,187,000 lower than the projected FY 1984 program

costs. We intend to fund this $19,187,000 from anticipated unobligated balances remaining at the end of FY 1983. The actual FY 1984 program costs are expected to be $413,000,000; a decrease of $22,000,000 from the comparable amount for program costs for this activity in FY 1983. Part of this decrease is contingent upon congressional passage of the President's proposed child support legislation, which is projected to save $10,000,000 in the Federal share of State and local administrative costs in FY 1984. The remainder of the savings is primarily due to an increase in the percentage of the caseload which is composed of Tax Intercept Program cases. These collections are made when, under certain circumstances, the IRS withholds tax refunds which are due to taxpayers in arrears to the government for child support payments in AFDC cases. The refunds are used to reduce these arrearages, and they represent an inexpensive and cost effective way to make collections.

Research and Evaluation

We are requesting $450,000 for research and evaluation grants and contracts under section 1110 of the Social Security Act, the same level as last year. These funds will be used to study ways to assess the ability of absent parents to pay child support, examine the interplay of joint custody and child support, and improve the information flow between AFDC and child support enforcement agencies.

Federal Administrative Expenses

The FY 1984 request includes $22,200,000 and 359 full-time permanent positions for Federal administration. This represents an increase of $1,273,000 over the FY 1983 level, and the same number of full-time permanent positions. The Office of Child Support Enforcement provides policy direction, technical assistance and guidance to State and local child support programs in addition to its monitoring and grants management functions. The increase of $1,273,000 is necessary to cover the costs of the full-year effect of the October 1982 payraise, within-grade raises, promotions, Medicare coverage and other mandatory increases.

The Office of Child Support Enforcement also performs reimbursable work for States. This reimbursable work requires 2 work-years and has an estimated cost of $90,000. This activity is authorized by the Federal Parent Kidnapping Act of 1980 (P.L. 96-211) which allows use of the Federal Parent Locator Service to locate parents with custody of a child in violation of a court order.

STATEMENT OF PHILLIP N. HAWKES

Mr. Chairman, members of the subcommittee, I appreciate the opportunity to discuss the refugee and entrant assistance programs of the Department of Health and Human Services, and the budget that we are proposing for them for FY 1984.

Although refugee resettlement is a tradition in this country, permanent federal programs for this purpose are relatively new. The Refugee Act of 1980, signed into law in March 1980, provides for the annual admission of refugees to this country and established the Refugee Assistance Program to enable and encourage these refugees to become self-sufficient as soon as possible. The Refugee Education Assistance Act of 1980 was passed at the end of FY 1980 in response to the emergencies associated with the unexpected arrival of Cuban and Haitian entrants in 1980. This Act established the Cuban/Haitian Entrant Program through which assistance is made available to the entrants, on the same basis as refugees, again for the purpose of enabling these individuals to become self-sufficient members of our society.

The FY 1984 budget request for refugee and entrant assistance is $485,328,000. This request is based on Congressional reauthorization of the Refugee Act of 1980, which expires at the end of FY 1983. This budget request is for a single appropriation for the Refugee Assistance and Cuban/Haitian Entrant Programs. We believe that a single appropriation is appropriate and necessary because of the similarity of the two programs and because of the need for flexibility in using program funds to assure the most effective resettlement of both populations. Such flexibility is critical due to the uncertainties in the arrival rate of refugees and in the assistance needs of the new and existing population.

This reduced request from the Congressionally approved FY 1983 funding level will be sufficient for FY 1984 on the basis of carry-over capacity from FY 1983 funds, reduced FY 1984 admissions and more restrictive eligibility criteria for cash and medical assistance.

There are six activities proposed under the refugee and entrant programs in FY 1984: State Administered Programs, State Per Capita Grant Programs, Cuban/Haitian Entrants Domestic Assistance, Preventive Health, Voluntary Agency Programs and Federal Administration. These may be summarized briefly as follows:

a) State Administered Programs. We are requesting $190,242,000 under this activity to provide Federal funds to reimburse the States' share of cash and medical assistance provided to refugees eligible for and receiving benefits under the programs Aid to Families with Dependent Children (AFDC), Medicaid (Title XIX of the Social Security Act), Supplemental Security Income (SSI) and State and local General Assistance (GA). Federal funds will be made available to match the State share of such costs during the 36-month period after the individual's arrival in this country. This activity will also make funds available for services for refugee unaccompanied minors as well as the related administrative costs of these activities.

For FY 1984, Federal cash and medical assistance for refugees otherwise ineligible under those categorical programs will now be provided under a per capita grant program in accordance with policies and procedures established by the State. This program will also provide for other special needs, such as social services, for refugees.

b) Per Capita Grant Programs

This request in the amount of $270,116,000 introduces a State per capita grant program to provide the following assistance and services at the discretion of the State: cash and medical assistance to non-categorically related refugees during the statutory period of 36 months from a refugee's

date of arrival in this country; education assistance to children; training and social services; and targeted assistance for areas of special needs.

The per capita grant program would replace Federal funding previously designated separately for:

- Special programs of refugee cash assistance (RCA) and refugee medical assistance (RMA) for needy refugees who do not meet the categorical requirements of existing programs under AFDC, Medicaid, SSI or GA,

- Social services,

- Targeted assistance, and

- Educational assistance for refugee school children.

For example, since FY 1980, approximately $103 million has been separately appropriated to aid refugee school children. Any future needs, above and beyond the already established capacity, would be provided for through the State's per capita grant.

Federal reimbursement would remain available at the 100% level for those cash and medical assistance costs which States are required to incur under existing AFDC, Medicaid, SSI, and GA programs through the State Administered Program activity.

The Administration is proposing a per capita grant program in an effort to provide States with the maximum flexibility to determine their priority needs in offsetting refugee impact and in promoting early refugee self-sufficiency. Without Federal allocation of funds restricted by line activity (e.g., cash and medical assistance, social services, education assistance and targeted assistance), the States will be in a position to provide quick, effective and more innovative responses to the needs of their refugee populations according to local situations, problems or special emergencies as determined by each State.

The amount requested represents the sum of the amounts that would have been requested for these items under the former budget lines, adjusted for anticipated refugee levels.

c) Cuban/Haitian Entrant Program

Under Section 501(a) of the Refugee Education Assistance Act of 1980, Cuban and Haitian Entrants are eligible for domestic assistance and services equivalent to that provided to refugees under the Refugee Act of 1980. We are requesting $5,928,000 for this program in FY 1984 to provide cash and medical assistance, social services, and related State administrative costs to support those Entrants who still retain program eligibility in FY 1984 as a result of their detention in Federal facilities. For these individuals, the 36-month period of program eligibility commences upon their release from Federal custody. This request also provides funds for entrant unaccompanied minors who have not attained the age of majority in FY 1984.

Section 501(c) of the Act also authorizes Federal funds for the reception and care of entrants in processing sites and camps where they undergo medical and security screening and await resettlement or placement in American communities. In FY 1984, the Department of Justice will continue to have this responsibility.

d) Preventive Health

This activity, for which we are requesting $8,450,000 in FY 1984, will fund two basic functions related to health care for refugees.

The first is to monitor the adequacy of medical screening conducted overseas and to assure appropriate follow-up and treatment of refugees with diseases which might be of concern to public health officials. This work will be conducted by Centers for Disease Control (CDC) personnel stationed overseas and at ports of entry. They will work to assure the continued quality of medical screening and disease surveillance overseas and the inspection and notification procedures at ports of entry.

The second function covers a modest grant program administered by CDC to support State and local health agencies which conduct health assessments and immediate follow-up care for a variety of conditions including skin infections, intestinal parasites, malnutrition, and anemia. In addition this activity will provide support to State and local health departments for follow-up and preventive treatment of refugees found to have tuberculous infection.

e) Voluntary Agency Programs

This activity provides matching funds on a dollar-for-dollar basis, up to a specified maximum of $1,000 per refugee to voluntary agencies for services in resettling refugees. The principal objective is to enable the refugees to become self-supporting and independent members of American society. Funds are provided primarily for the resettlement of non-Far-Eastern refugees. A wide range of activities is covered including training, recertification in the United States for professionals trained abroad, social services, maintenance assistance, and health care. Funding is provided for this activity in lieu of regular State administered cash and medical assistance and social services.

We are requesting $4 million for this program in FY 1984.

f) Federal Administration

The Office of Refugee Resettlement (ORR) was established by the Refugee Act of 1980 to be responsible for the management of the domestic refugee resettlement program. We are requesting $6,592,000 in FY 1984 under this activity to administer the annual appropriation for refugee and entrant assistance, to monitor the recipients of Federal grants under the Refugee Resettlement Program and the Cuban/Haitian Entrant Program, both fiscally and programmatically, and to develop and implement national initiatives (such as case management and favorable site placements) in response to problems in domestic resettlement.

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Questions Submitted by the Subcommittee

DECLINE IN SSI ROLLS

Question: The number of persons enrolled in the Supplemental Security Income program (SSI) peaked at 4.3 million in FY 1976, then began to recede slowly. In July 1982, it fell to 3.9 million, the lowest number since late 1974, the first year of the program. What effect will the continuing decline in Supplemental Security Income enrollment have on Federal outlays in the next few years?

Answer: SSI enrollment of Federal beneficiaries (exclusive of the impact of the Social Security Amendments of 1983) is expected to decline from 3,450,000 in FY 1983 to 3,355,000 in FY 1984. The resultant reduction in costs will be more than offset by the projected increases in average benefits caused by the automatic cost-of-living adjustment, and the increases in the SSI payment standard, causing Federal outlays for SSI to increase over the next few years.

Question: Does the drop in the number of SSI applicants since 1976 reflect greater coverage by Social Security and/or higher benefits from Social Security?

Answer: Both of these factors--greater coverage by Social Security and higher benefits--have reduced the SSI caseload. SSI applicants, in general, have more income and assets than they did in 1974 and consequently, fewer are eligible for benefits.

Question: Why has the proportion of new enrollees who are disabled climbed steadily--from less than half in 1974 to two-thirds today?

Answer: Approximately 61 percent of the FY 1982 Federal caseload is either blind or disabled. Three major factors account for the growth in the blind/disabled category from 1974 to the present. First, many disabled SSI recipients have had sporadic work histories and are therefore unlikely to be successfully rehabilitated back into the work force. Secondly, approximately 18 percent of all blind/disabled recipients are, in fact, over age 65; however, they are not reclassified as aged recipients in the SSI program. A blind or disabled individual's payment amount is not affected by attainment of age 65; SSA does not reclassify these individuals because the aged, blind and disabled are treated differently in some States for supplementation purposes. This inhibits the growth of the aged category while serving to maintain the stability of the blind/disabled category. Third, there has been an increase in the number of SSI disabled children. In general, the impairments of these children tend to be severe and accordingly, they stay on the program for a long period of time. From FY 1983 to FY 1984, SSA is projecting only a slight decline in the number of blind and disabled recipients.

SSI RECIPIENTS RECEIVING VR SERVICES

Question: The Omnibus Budget Reconciliation Act of 1981 permits use of Supplemental Security Income (SSI) funds to

reimburse vocational rehabilitation agencies only for services given to disabled SSI recipients who thereafter succeed in performing substantial gainful activity for a continuous period of 9 months. How sharply have States cut back efforts to rehabilitate disabled Supplemental Security Income (SSI) recipients in view of the new law limiting reimbursement from SSI funds to "successful" cases?

Answer: The Reconciliation Act provision that allows reimbursement for successful rehabilitation of SSI recipients is a bonus to States for funds already provided under the Basic State Grants program administered by the Department of Education. Under that program, the law requires that the most severely disabled have priority in receiving vocational rehabilitation (VR) services, and SSI beneficiaries are, by definition, among that group. We do know that States have had to reduce the overall level of VR services provided, but we do not have specific numbers for SSI recipients served. However, they should not be denied services solely because of the specifics of SSA's reimbursement program.

Question: How many disabled SSI recipients received rehabilitation services in fiscal 1981 and 1982?

Answer: Under the VR program prior to the 1981 Reconciliation Act, the Rehabilitation Services Administration (RSA) managed SSA's VR programs. Beginning in fiscal 1980, data collection forms were being revised within the Administration and RSA could not collect data from the States on the number of SSA beneficiaries who were being served. Thus, we don't know how many SSI recipients received VR services in 1981 or 1982. In 1982, SSA began managing the new VR program that provides reimbursement for State costs of successful rehabilitations. When we have verified all State claims for 1982 successes, we can determine how many SSI recipients received VR services and were rehabilitated successfully.

Question: What is the forecast for fiscal 1983 and 1984?

Answer: Once we have actual 1982 data for the VR program we will be able to predict the number of successful rehabilitations in 1983 and 1984. RSA has recently begun again to collect data on persons receiving VR services, so a count of SSI recipients receiving such services should be available in the future from that agency.

Question: For what disabling conditions have rehabilitative efforts been most successful? Least successful?

Answer: Under the new SSA VR program, we have not yet gained enough experience to determine those conditions which are most affected by rehabilitation efforts. Once we have comprehensive data on 1982 successful rehabilitations, we will be able to make evaluations on which conditions were corrected.

Question: Under the new restriction on reimbursement, what incentive have States to serve SSI recipients whose disabilities are hardest to overcome?

Answer: The basic Federal rehabilitation program is the Basic State Grants program which is administered by the Department of Education. By law, priority is given to providing services to those with the most severe disabilities. This group includes SSI recipients, because the SSI definition of disability is a very strict one. SSA's reimbursement for costs of successful rehabilitation is merely a supplement to the 80 percent matching funds that the States receive under the basic program. Thus, the States are still mandated to serve SSA's severely disabled SSI recipients, but now they can receive additional funds from SSA if a successful rehabilitation (as defined by the law) is produced.

REVIEW OF DISABILITY CASES

Question: When you review disability cases, what efforts are you making to insure that only those individuals who are not truly disabled will have their benefits terminated?

Answer: SSA has a number of procedures in place to better insure that only those individuals who are truly disabled will not have their benefits terminated. Since October 1982, we have been conducting face-to-face interviews with each beneficiary scheduled for review to explain the individual's rights and responsibilities, and to eliminate obviously unnecessary investigations. We are developing special disability expertise in some local SSA offices with the highest continuing disability investigations (CDI) workloads. In gathering medical evidence, SSA has mandated that States review all evidence available in the past 12 months, and we will pay for special examinations if evidence of record is incomplete. SSA also targets quality assurance reviews of cessation decisions to these categories that are most error-prone, and we give highest priority to handling appeals of cessation cases. We are also broadening the definition of permanent disability, which will reduce the number of beneficiaries subject to CDI's.

In addition, Congress has recently passed legislation which permits continued payment of benefits through the hearing decision in cessation cases, and establishes a face-to-face evidentiary hearing in CDI reconsiderations. SSA has implemented the first and is preparing to begin the second in fiscal year 1984.

AFDC FISCAL SANCTIONS

Question: Which States are failing to meet the law's target of reducing payment error rates in the program of Aid to Families with Dependent Children to 4 percent for fiscal 1983?

Answer: The FY 1983 error rate information will not be available until late FY 1984.

Question: When will fiscal sanctions be imposed on them, and how?

Answer: Fiscal sanctions may be imposed on them in late FY 1984 or early FY 1985. These sanctions will take the form of disallowances and will follow the same procedure presently in

use. The State's grant will be adjusted for the period of the disallowance which has the effect of reducing available funds for the current year.

Question: How much are sanctions estimated to be in each fiscal years 1983 and 1984?

Answer: The sanctions for FY 1983 and FY 1984 are estimated to be $114 million and $156 million respectively. The budget assumes collection of these amounts in FY 1984 and FY 1985 respectively.

Question: How did implementation of changes enacted in the 1981 reconciliation legislation affect payment error rates in the Aid to Families with Dependent Children program?

Answer: In order to eliminate any disincentives to prompt implementation of provisions of the Omnibus Budget Reconciliation Act of 1981 (OBRA), we modified the quality control review procedures to provide that errors made by the agency in implementing OBRA would not be counted against them through March 1983. The error rates for the first period affected by OBRA (FY 1982) will not be available until September 1983.

Question: What was the national average payment error rate in fiscal 1982?

Answer: The congressional mandated error rates on the States for FY 1982 would result in a 5.8 percent national error rate. Our projections based on State trends, however, indicate that all States will not meet their mandated targets, resulting in a national error rate of 6.1 percent for FY 1982.

Question: What is it estimated to be in fiscal 1983? FY 1984?

Answer: For FY 1983 and FY 1984, we project that State performance will continue to improve, but that all States will not meet their mandated targets. We project national average error rates of 5.7 percent in FY 1983 and 5.3 percent in FY 1984.

CHILD SUPPORT ENFORCEMENT PROPOSALS

Question: What suggestions do you have to make this program more cost effective for the Federal Government?

Answer: By strengthening the program, everyone will realize a financial gain in the long-term: the Federal Government, the States, and the women and children who are the program's primary beneficiaries. The record compiled by the better performing States as well as academic studies indicates that the primary barrier to be overcome is the absence of and the failure to use effective child support enforcement techniques.

The Administration's legislative proposals are aimed at making a good program better by offering a stimulus for improved program performance. We would establish a clear relationship between program financing and performance, give tangible

recognition to exemplary performance, and allow adequate time for States to make the transition to a new and sounder mode of operation. In addition, we would extend to all States the use of certain practices which have been tried by some States and shown to be successful in improving the effectiveness of their child support enforcement programs. And, States would be encouraged to tailor implementation to their own peculiar circumstances and to continue to develop innovative program improvement techniques.

Question: What would be your reaction to lowering the Federal matching rate, which under current law requires Federal funding to pay 70 percent of administrative costs?

Answer: Our position is that reducing the Federal matching rate is more likely to produce a smaller child support enforcement program rather than a better one. At a time of fiscal stringency, some States may well be unable or unwilling to replace diminished Federal funding in order to maintain, much less improve, their child support enforcement programs.

More importantly, changing the matching rate does not come to grips with the fact that under the current program financing mechanism, financing and program performance are only loosely related, marginal program efforts are financially rewarded, and open-ended administrative funding encourages the refinancing of ongoing State and local activities. These are structural problems; they are not resolved by another reduction in the Federal matching rate.

Reducing the matching rate does seem to have the temporary effect of lowering the program deficit being borne by the Federal Government. We would stress the temporary effect, however. Over time this effect is dissipated and at best it operates in an indiscriminate way, hurting all States irrespective of their program performance. The Administration's proposal, on the other hand, by directly addressing the structure of program financing encourages and rewards improved performance.

REDUCTION IN FUNDING FOR REFUGEE PROGRAMS

Question: You propose cutting appropriations for refugee and entrant assistance by $100 million, down to $485 million in fiscal year 1984. Yet your budget makes no mention of such factors as unemployment among refugees, or the actual cost of educational and training assistance necessary to help them obtain permanent employment. Why have you chosen to focus on an anticipated decline in the eligible refugee population, without indicating the extent to which funding is actually needed to meet the costs of essential services?

Answer: An apparent reduction of $100 million in FY 1984 for refugee and entrant domestic assistance is misleading. During FY 1983, Congress recognized special program conditions which resulted in a one-time increase of $55 million in targeted assistance to meet special refugee and entrant needs in impacted areas and a $21 million increase in social services funds. Beyond those two factors, the reduced FY 1984 request is based upon the reduced FY 1984 refugee flows and the substantially reduced

refugee and entrant population eligible for services and assistance due to the 36- and 18-month limitations.

For purposes of budget formulation of a nonentitlement program, the universe of the eligible population to be served in the fiscal year provides a more reliable base to determine budgetary needs than consideration of such factors as unemployment and training needs of the refugee and entrant populations as a whole.

STATE COSTS FOR REFUGEE EDUCATION

Question: What is the actual cost being borne by the States for the education of refugee and entrant children, as well as for providing social services mandated by law?

Answer: An estimate of the educational costs was contained in a report to the Congress entitled Report on Costs for Refugees and Cuban and Haitian Entrants, prepared by the Office of the U.S. Coordinator for Refugee Affairs and dated October 25, 1982. The coordinator's estimate of total State/local education costs for FY 1982 was $247.7 million. However, the Department of Health and Human Services only reimburses States for the costs of special curriculum materials, bilingual teachers and aides, remedial classes, guidance and counselling required to bring these children into the mainstream of the American education system. Since FY 1980, approximately $103 million has been appropriated for these purposes. No estimate is available for social service costs; however, it should be noted that a State may charge against its Federal grant from the Office of Refugee Resettlement the cost of any social service provided to a refugee which is permissible under its social service program under title XX of the Social Security Act.

EMPLOYMENT AND TRAINING ASSISTANCE FOR REFUGEES AND ENTRANTS

Question: How many refugee and Cuban-Haitian entrants will be provided employment and training assistance under your proposed budget and at what cost?

Answer: Under the Federal per capita grant program States will have discretion to allocate funds as they see fit for a range of activities including employment and training assistance. The unit cost per refugee or entrant for employment and training assistance is currently estimated at $660. Each State will have the option, at its own discretion, to direct any or all of these grant resources to meet those refugee and entrant needs determined to be most immediate and critical. Therefore, we are unable to provide a national numeric estimate on the number of refugees and entrants actually receiving these services in FY 1984. This will be determined on a State-by-State basis according to refugee and entrant needs.

PER CAPITA BLOCK GRANT FOR REFUGEE PROGRAMS

Question: Since the Refugee Act expires at the end of FY 1983, when do you plan to submit proposed new authorizing legislation to create a new "per capita" block grant program?

Answer: A reauthorization bill is being prepared at this time and will be submitted to the authorizing committees as soon as possible.

Question: If the existing programs are simply extended for another year, what specific funding levels would you recommend for fiscal 1984?

Answer: If the existing programs of refugee and entrant assistance are extended into FY 1984, the following funding levels are recommended on the basis of reduced flows and the 36- and 18-month limitation on refugee and entrant cash and medical assistance:

	(000)
State-Administered Programs (cash & medical assistance, State administration)	$351,222
Social Services	57,536
Subtotal, State-Administered Programs	$408,758
Targeted Assistance	35,000
Educational Assistance for Children	16,600
Cuban/Haitian Entrant Domestic Assistance	5,928
Preventive Health	8,450
Voluntary Agency Programs	4,000
Federal Administration	6,592
Total	$485,328

Question: What assurances would there be that specific services mandated by the Refugee Act, such as language training, employment assistance, and cash and medical assistance, would be funded under a block grant?

Answer: While there would be no specific requirements as to the types and amounts of assistance and services to be provided under the per capita grant, we believe that States will use those funds to achieve refugee self-support as quickly as possible. There is a major incentive for States to do this since extended refugee dependency, beyond the time limits during which Federal refugee funding for assistance is provided, would become a burden on State and local resources.

Question: Would there be a tendency in this new program to shift refugees from the refugee-specific programs covered by the block grant to the categorical programs for which States would be assured of 100 percent reimbursement?

Answer: The requirement under present policy is that refugees who are eligible for the programs of Aid to Families with

Dependent Children (AFDC), Medicaid, and Supplemental Security Income (SSI) be placed on those programs. There is also an expectation that refugees who are eligible under State or local general assistance (GA) programs would be placed on those programs when their eligibility for the special program of refugee cash assistance (RCA) has expired after 18 months in the U.S. We anticipate tht a number of States may seek to shift eligible refugees from the per capita grant program to GA programs during their first 18 months in the U.S.

Question: If so, is this good or bad? Does the proposal on page 21 of the budget justification reimburse for general assistance programs to a full 36 months?

Answer: We would consider this change desirable since we believe it is appropriate, to the fullest extent possible, for refugees to be aided under the same programs and according to the same rules that apply to U.S. citizens in similar circumstances. Under the proposal, a State could claim reimbursement for general assistance (GA) costs for a refugee's first 36 months in the U.S.

Question: Why is this budget based on a refugee entrant figure of 82,000 when the Department of State Migration and Assistance Budget is based on a FY 84 level of 72,000 refugees? How does this affect the overall budget figures?

Answer: ORR's FY 1984 budget request is based upon the 1984 admission levels established at the time of DHHS' budget formulation process. The Department of State's budget apparently is based upon a later revised figure established within that Department. A reduction of 10,000 in FY 1984 admission levels would reduce ORR's total program needs approximately $10 million. We believe that it would be premature to adjust the refugee budget now because the refugee ceiling figure may be revised again by the State Department in September.

Question: What formula are you proposing for State-by-State distribution of "per capita" block grant funding?

Answer: The details of the Administration's bill are still being worked out.

Question: How will you ensure that States heavily impacted by refugees and entrants receive adequate assistance?

Answer: Since the funds would be awarded on a population basis and since the States would have maximum flexibility in determining the uses of the funds, within the purposes and uses authorized by the Refugee Act, we believe that adequate provision would be made for all States to address their particular refugee situations in the most effective manner. Since the population estimates would take secondary migration into account, the amount of funds which a State would receive would reflect its actual refugee population.

OVERSEAS MEDICAL EXAMINATIONS FOR REFUGEES

Question: Last fall, GAO recommended that overseas medical examination of refugees be improved, that treatment for certain diseases be initiated and completed overseas before refugees are allowed to enter the United States, and that medical waivers be granted only when there are compelling reasons to do so. In order to minimize the financial burden on local health departments and reduce future public health problems, has any action been taken by the Department of Health and Human Services to revise its policies regarding overseas medical examination and treatment procedures for Indochinese refugees entering the United States?

Answer: The Department of Health and Human Services has made the following changes in the overseas processing of Southeast Asian refugees who will be resettled in the United States:

Tuberculosis: As Southeast Asian refugees are now staying at the refugee processing centers overseas for a longer period to attend special language and cultural orientation courses, the CDC instituted, on December 1, 1982, an intensive 6-month treatment regimen for U.S.-bound refugees diagnosed as having active tuberculosis. Under this procedure, most Southeast Asian refugees will now complete their TB treatment prior to entering the United States.

Chest X-rays are now performed on all Southeast Asian refugees age 2 and older. Previously, X-rays were performed for all refugees above age 14 and those younger refugees who were family contacts of active cases. Results of this screening of all children age 2 through 14 will be reviewed periodically to determine whether chest X-ray examination of all children in this age group is necessary and therefore should continue.

In January, sputum cultures were initiated in Thailand on a pilot basis to assist in the diagnosis and classification of TB in refugees suspected as having active disease. The performance of cultures may be expanded to more of the refugee processing centers in Southeast Asia after evaluation of the results of this study have been completed.

Tuberculin skin testing and chemoprophylaxis of reactors are expected to be started by the end of FY 1983.

Hepatitis B: In the very near future, screening for the presence of hepatitis B surface antigen, the test for hepatitis B carrier state, will be conducted in the pregnant women and unaccompanied minors. Pregnant carriers will be identified so that their newborns can be passively protected with immune gloubin. Unaccompanied minors who are carriers will be identified so that their foster families who will be close household contacts in the U.S. can be protected by vaccination, if they desire it.

Physical Examination: The Intergovernmental Committee for Migration (ICM), the State Department contractor which conducts the medical screening examinations overseas, has initiated a new

standard physical examination, at our request, which would satisfy the medical screening requirements of all countries for which they perform medical examinations. This examination includes:

- o Medical history and review of medical records;
- o Blood pressure and pulse;
- o Physical examination, including examination of complete body surface with special attention to the hands and feet, examination of the eyes, ears, nose and throat, auscultation of heart and lungs, and palpation of glands and abdomen;
- o Brief neurologic check;
- o Chest X-ray; and
- o Serology for syphilis (14 years and above).

Medical Records: Medical records from first asylum camps are now provided to ICM at the time of screening and made a part of the refugee's records at the time they depart for the United States.

EDUCATION PROGRAMS FOR REFUGEE CHILDREN

Question: How will the education program for refugee children be affected by the Administration's request that no specific appropriations be made for refugee children education in fiscal year 1984?

Answer: In developing the total request for the per capita grant to States, the previous level of funding for educational assistance was taken into account. Therefore funds are included in the per capita grant based on estimated educational needs. Each State would of course determine the proportion of its per capita grant to be used for educational assistance for children.

Question: What mechanisms are in place to meet the special educational needs of refugee children?

Answer: Congress indicated its intent that $16.6 million of the funds contained in the Continuing Resolution for FY 1983 be used for educational assistance for refugee children. As in previous years, these funds are being transferred to the Department of Education by HHS and will be allocated under that Department's regulations for the program of educational assistance for refugee children.

Question: How will the education program for Cuban/Haitian Entrant children be affected by the Administration's request that no appropriations be made for Cuban/Haitian Entrant Education in FY 1983?

Answer: For FY 1983, Cuban/Haitian Entrant education assistance for children is being funded out of appropriations made available under Targeted Assistance. Of the $75 million made

available under that activity, $5 million is specifically set aside for Entrant children educational assistance.

Question: What mechanisms are in place to meet the special educational needs of Cuban/Haitian Entrant children?

Answer: Congress included $5 million in the Continuing Resolution for aid on behalf of the education of Cuban and Haitian Entrant children. Under an interagency agreement with the Department of Health and Human Services, these funds are being made available through the Department of Education.

Question: What provisions have you made in this budget to reflect the fact that there is a secondary migration of refugees, such as from California to Oregon, which is severely impacting local educational agencies due to the increasing number of refugee children?

Answer: We are unaware of any significant patterns of refugee secondary migration from other States, such as from California into the State of Oregon.

IMPACT OF SOCIAL SECURITY LEGISLATION ON SYSTEMS MODERNIZATION

Question: What impact will the recently passed Social Security "bail-out" legislation have on delaying your computer systems modernization plan by introducing so many programmatic changes?

Answer: SSA is presently reassessing its previous evaluation of this legislation based upon the changes made in the final version of the bill. Based upon our preliminary assessment we do anticipate some impact upon the overall plan though it won't be major. These legislative workloads will impact mostly software related initiatives, requiring some minor adjustments to individual project efforts for software improvement and redesign initiatives in the Software Engineering Program. Special projects are being established to facilitate additional analysis and implementation planning. The greatest impact on modernization activities appears to be in our software improvement area where contracts have already been awarded to effect improvements. At the present time it appears we will have to retrofit improved software with new legislation. In addition, SSA plans to limit other user enhancement projects, rather than SMP projects, in favor of implementing legislation. Since most changes caused by legislation will be assigned to staff charged with software maintenance, maximum attention will remain focused on the SMP. We will also consider the additional use of contractual resources to implement some provisions of the legislation.

REVISED APPROPRIATION REQUESTS DUE TO SOCIAL SECURITY LEGISLATION

Question: When do you expect to have revised fiscal 1984 estimates of amounts necessary for appropriated entitlements affected by the Social Security legislation? Please provide these revised appropriations for the record.

Answer: SSA has developed estimates of the effect of the Social Security legislation on the appropriations for the Supplemental Security Income Program, the Payments to the Social Security Trust Funds and the Limitation on Administrative Expenses. A package of proposed 1984 Budget Amendments and 1983 Supplemental Requests is under review within the Executive Branch. When these revisions to SSA's appropriations are reviewed and approved by OMB, we will forward them to the Committee.

IMPLEMENTATION OF SOCIAL SECURITY LEGISLATION

Question: The recently enacted Social Security Act Amendments of 1983 contain major program changes which apparently call for major systems changes, which, in turn, will require substantial ADP resources. Concern has been expressed that in order to implement these provisions SSA will probably have to divert ADP resources away from systems modernization activities as well as from important cyclical workloads. In this regard, please explain in detail (1) how SSA plans to implement these provisions, (2) the associated resources that will be required, both during the "start-up" periods prior to provision effective dates and thereafter, and (3) the resulting impacts of implementation on ongoing agency operations and current and planned systems modernization activities. In describing required resources, please account for both ADP and resources which will need to be redirected from other agency activities and workloads (these activities and workloads and the resulting impact thereon are to be clearly identified) and those additional resources which the Congress will need to provide.

Answer: Implementation and ongoing administration of the new Social Security legislation will increase workloads for SSA's operations and systems. However, detailed planning has not yet been completed and the Administration is in the process of identifying the level of additional resources needed as a part of a package of 1984 Budget Amendments and 1983 Supplemental Requests. These revisions are currently under review by the Secretary.

The following provisions are the major ones expected to involve administrative costs:

-- taxation of OASDI benefits which requires SSA to provide statements of benefits to Social Security beneficiaries who are potentially subject to taxation of benefits;

-- increase in the SSI benefit standard which will increase the number of SSI claims and recipients;

-- notification to elderly Social Security recipients of the availability of SSI (entails notification costs and is expected to increase the number of SSI claims and SSI recipients);

-- special provisions on aliens (at least initially, entails manual processing to withhold taxes from Social Security

benefits of nonresident aliens and suspension of benefits to dependents or survivors who live outside the United States for 6 consecutive months).

At the present time, we do not anticipate that implementation of the legislation will have an adverse impact on the Systems Modernization Plan because we are considering use of contractual support to augment SSA systems resources available to implement the legislation.

DEBT MANAGEMENT

Question: What are the basic features of the Social Security Administration's debt management program aimed at recouping overpayments of Social Security benefits?

Answer: Basically we are trying to identify and process overpayments more rapidly and collect a greater portion of the debt we clear. Specific features include:

-- elimination and prevention of delinquent debts,

-- enforcement of the annual earnings test through timely reconciliation of beneficiary earnings reports with annual wage reports received from employers (Forms W-2),

-- automation of the SSI overpayment notices to move debts to resolution more quickly,

-- shorten average recovery period by approving lump sum and installment repayment plans appropriate to the situation,

-- implementation of an automated billing and follow-up system to improve controls and likelihood of recovering debts from individuals no longer eligible for benefits, and

-- development of a National Debt Management System to, among other things, enhance controls over and accountability for all debts owed by current and former beneficiaries.

In pursuing recovery, SSA will continue to recognize the overpaid individual's rights to due process, waiver and repayment terms consistent with their ability to repay.

Question: What has your experience been to date with this initiative?

Answer: The results of our debt collection initiative have been excellent. SSA collected almost $1 billion in FY 1982 which was 53 percent higher than the $635 million collected in the previous year. Collections for the first 5 months of FY 1983 are $450 million, or $153 million (52 percent) higher than the comparable period in FY 1982. Increases in both years are the result of our working to reduce the delinquent backlogs, shortening recovery periods, reinstating earnings enforcement operations and implementing the SSI windfall offset provision of the 1980 Amendments.

Question: What safeguards are in place to insure that the program is cost effective and that beneficiary rights are protected?

Answer: While SSA is making a major effort to recover overpayments, it also will continue to recognize the overpaid individuals's right to (1) due process, (2) waiver when statutory requirements are met, and (3) negotiation of reasonable installment or compromise settlements. We hope that our efforts in this area will raise the public's confidence in the quality of our program administration and our effectiveness in safeguarding trust fund assets. The initiative has been cost effective to date. For example, in FY 1982 SSA collected $4.40 for each one dollar spent in collection activities and only spent 23 cents to collect each dollar. Comparable figures for FY 1981 were $4.26 per dollar invested and 23 cents to collect one dollar. Examples of some efforts to further reduce costs follow:

-- consolidation of the overpayment processing operations in the six program service centers (PSC),

-- automation of the remittance processing, billing, dunning and telephone processes,

-- implementation of "folderless" processing in the PSC overpayment units, and

-- termination of recovery efforts in those cases where the overpayment is clearly uncollectable.

Question: What are you doing to improve debt prevention and thus minimize debt collection problems in the future?

Answer: Most overpayments occur because of beneficiary misreporting, such as discrepancies between annual earnings reports and income information on W-2 forms. As a result, there will always be some level of "incorrect" benefit payments. However, the agency is making an active effort to improve payment accuracy in both the title II and title XVI programs. Specific initiatives are:

--front end review of State agency disability determinations (required by 1980 Disability Amendments)

--a cooperative effort with IRS to identify interest from undisclosed bank accounts to correct nondisability errors in SSI payments.

--ongoing reviews of initial awards and subsequent changes eliminate technical errors in benefit payments.

RECONSIDERATION AND HEARING PROCESS

Question: We understand that about 12 percent of those who ask the Social Security Administration to reconsider denial of benefits have the initial decision reversed. However, more than half of the remaining 88 percent that then ask for a formal hearing to protest the negative reconsideration decision are

successful in getting Administrative Law Judges to rule them eligible for benefits.

Doesn't this indicate that the reconsideration process is largely ineffective, or are Administrative Law Judges too lenient in allowing Social Security benefits?

Answer: The discrepancies you describe in the appeals process are largely limited to disability cases, which, as you know, constitute the large majority of cases at all levels of the appeals process. These discrepancies are most pronounced in disability termination cases. We recognize the particular need to improve the reconsideration process in these cases, and believe that the face-to-face evidentiary hearing required by P.L. 97-455 at the reconsideration level will be a significant improvement. We plan to begin nationwide implementation of the new reconsideration process on October 1, 1984. A pilot project is now underway in three States--California, New Mexico and Texas--to evaluate the advantages of a face-to-face reconsideration hearing in disability termination cases.

The high rate of allowances at the Administrative Law Judge (ALJ) hearing level can be attributed to a number of factors, including the availability of new evidence at that level and the fact that the ALJ hearing has been the first opportunity for face-to-face contact in the appeals process. We anticipate a very beneficial impact from the new reconsideration hearing process, both because a greater number of termination appeals will be resolved at the reconsideration level and because of improvements in case record development at the lower levels.

One factor which has to some extent contributed to inconsistencies in the disability appeals process has been the lack of a consistent set of adjudicatory standards for decisionmakers at all levels to follow. This problem will be remedied by the recent issuance of a series of Social Security Rulings on disability which for the first time provide definitive agency policy on a number of important disability issues. These rulings are in accordance with existing laws and regulations and do not establish new standards.

Question: What action are you taking to improve the appeals process for those who protest denial of Social Security benefits?

Answer: The most significant problems in the appeals process are in the disability programs. In response to the previous question, we described the improvements expected to result from the reconsideration-level hearing procedure required by P.L. 97-455 in disability termination cases. We also noted the importance of the recent series of Social Security Rulings on Disability, which will for the first time provide definitive agency policy on a number of important disability issues.

Another improvement for protecting the rights of beneficiaries in disability termination cases is the opportunity to have benefit payments continued until the issuance of an ALJ hearing decision, as provided by P.L. 97-455. The Administration supported this legislation.

We have also taken a number of steps specifically aimed at improving the timeliness and quality of case processing at the ALJ hearing level.

Question: We understand the hearing backlog is now in excess of 6 months. What plans do you have to reduce the badly backlogged caseload for Administrative Law Judges?

Answer: The budget includes several initiatives aimed at reducing the number of pending ALJ hearings requests. As already mentioned, the improved reconsideration procedure in disability termination cases will have a favorable impact at the ALJ hearing level, both by allowing a greater number of appeals to be resolved at the reconsideration level and by improving development of case records prior to the ALJ hearing level. In addition, we have hired more than 140 new ALJ's during the past 2 years and we now have a corps of over 800 ALJ's. We plan to maintain that number of ALJ's and increase the number of support staff to a support staff-to-ALJ ratio of 5:1. Experience has shown that the availability of a suffient number of support staff is an essential factor in improving the timeliness and quality of case processing by the ALJ's. This is due to greater staff involvement in pre-hearing case development and post-hearing activities, thus allowing the ALJ's to concentrate more fully on hearing cases.

We recently procured improved word processing and dictating equipment for the ALJ hearing offices. Along with the increases in support staff, this new equipment should contribute significantly to greater productivity in these offices. We have also encouraged improved staffing arrangements in these offices to make more efficient use of the support staff. Finally, we have improved and increased the availability of training both for ALJ's and their support staffs.

REFUGEE SERVICES PROVIDED BY VOLUNTARY AGENCIES

Question: Does the Office of Refugee Resettlement know the extent to which services provided by the voluntary agencies under this program overlap or supplement those funded by the State Department?

Answer: Voluntary agencies give assurance to ORR that services provided by the matching grant program do not duplicate services funded by the State Department Reception and Processing grant. The matching grant is intended to, and to our knowledge does, fund services not provided by the Reception and Processing grant.

Question: To what extent do voluntary agencies provide specific services or simply refer refugees elsewhere such as to ORR-funded State agencies and contractors?

Answer: We know that agencies which provide services, at the full match level, do not generally refer refugees to ORR-funded State agencies and contractors. Other agencies provide a selection of services at various locations across the country. Voluntary agencies participating in the matching grant program are

given the flexibility to determine which services they can best provide in each location. Where it is not cost effective to run a separate program for a particular service, e.g., English as second language classes for five matching grant refugees, the agencies do refer them to ORR-funded State services. At the same time, if other services can best be provided by the voluntary agency in a cost effective manner, the agency will provide those services with the support of the matching grant. For monitoring purposes, ORR requires that agencies show which services they provide in each location.

Question: To what extent have voluntary agencies under the matching grant program placed emphasis on quick employment and self-sufficiency?

Answer: The need and importance of early employment and self-sufficiency for refugees has been the subject of ongoing consultation and emphasis with the voluntary agencies and are stated in ORR's draft guidelines on matching grants. The agencies have begun to report employment data to ORR through regular progress reports; however, this project is in its earliest stages of implementation and definitive outcome measures are not as yet available.

REFUGEES RECEIVING PUBLIC ASSISTANCE

Question: Does ORR know what percentage of refugees assisted through the matching grant program also require public assistance?

Answer: ORR has requested that matching grant agencies collect and report data on use of public assistance by refugees served under the matching grant program. Reporting on this data is a condition of the grant award as of April 1, 1983. However, the first report to contain this information will not be due until November 1, 1983. While we do not have any hard data on use of public assistance by matching grant refugees at this time, we do know that two agencies, the Council of Jewish Federations and Rav Tov, are reimbursed at the maximum of $1,000 per refugee and at that level are able to provide a sufficient level of services to prevent employable refugees from accessing public assistance.

MONITORING REFUGEE PROGRAM GRANTEES

Question: To what extent does ORR monitor the performance of its grantees under the matching grant program?

Answer: ORR monitors the agencies in the matching grant program in several ways. The normal process for grant monitoring involves ongoing contact between ORR project and grant specialists and the grantees. ORR receives semiannual program progress reports and quarterly financial reports from the matching grant agencies. Reviewing and discussing these reports with the grantee is part of the continuous monitoring process. In 1982, an ORR-funded evaluation study of the matching grant program was completed. This study reported that the matching grant program was essentially healthy; its main recommendations for monitoring were directed toward refinement of program guidelines. ORR is writing new program guidelines for the fiscal year 1984 grants.

In addition, we have established a schedule for on-site financial and program monitoring of all matching grantees which will be completed by July 30 of this year.

RESETTLEMENT OF HAITIANS FROM DETENTION CENTERS

Question: What assistance has the Office of Refugee Resettlement made available for the settlement of Haitians who were released from detention last summer so that they will not be burdens to receiving communities?

Answer: ORR provided grants to those voluntary agencies resettling Haitians from Krome North, Fort Allen, and other Federal holding facilities to cover reimbursement for medical insurance for a period of 6 months as well as reimbursement for administrative costs associated with the processing and placement of Haitian detainees. Voluntary agencies agreed to assume maintenance costs for resettled Haitians for a period of 120 days and committed themselves to supporting Haitian detainees/parolees so as to minimize their utilization of public welfare. Very few Haitian detainees accessed welfare during that period. Subsequent to the expiration of the 120-day period, the INS declined to support the agencies in providing maintenance services to Haitian parolees. With the transfer of the Cuban/Haitian resettlement program to the Community Relations Service/DOJ, decisions regarding further support of Haitians through the voluntary agencies will be made by that agency in consultation with the INS. ORR's total expenditure for this program was about $1.3 million.

If the Department of Justice can arrange no further maintenance support through the voluntary agencies, entrants will still qualify for public assistance under the terms of the Fascell-Stone amendment, which authorizes ORR to reimburse the States for costs of cash and medical assistance provided to them for 36 months after their parole.

Question: How many Haitians who were released from Federal detention last summer are receiving Federal benefits and what efforts have been made to secure employment for this group?

Answer: Approximately 400 Haitians released from Federal detention last summer are currently receiving Federal benefits; e.g., cash and medical assistance. During the initial 120-day period for which the voluntary agencies had formal responsibility for the care and maintenance of Haitians, approximately 25 - 30 percent of those placed by the agencies became employed. Because of the requirement imposed upon the agencies and voluntarily accepted by them, that maintenance costs would be borne by the agencies, the voluntary sector made maximum effort to secure jobs for their caseload. At present, with the absence of direct support to the agencies, efforts to secure employment for the Haitian placements would be the responsibility of the receiving States using social service funds provided by ORR.

STAFFING REDUCTIONS IN OFFICE OF REFUGEE RESETTLEMENT

Question: How many of the anticipated fiscal year 1983 staff reductions in the Office of Refugee Resettlement (ORR) have been achieved?

Answer: ORR has reduced its 102 position staffing level at the start of the fiscal year by 14 positions. Current staffing has dropped to 88 employees with 2 positions vacant.

Question: Is the staffing sufficient to carry out the monitoring evaluation and reporting mandates of the Refugee Act and the Refugee Assistance Amendments of 1982?

Answer: Staffing resources are sufficient to carry out the monitoring and reporting requirements prescribed by both the Refugee Act and the 1982 amendments. ORR has developed workplans which account for these responsibilities and has allocated time accordingly. Moreover, by a more efficient use of the staff of field offices and improved internal management procedures, ORR expects to stretch its resources to meet the formal obligations conferred upon the agency. For example, both financial and program reporting requirements have been set in place. In order to obviate the need for staff intensive monitoring of individual projects, ORR is concentrating on an improvement of State management of the program and corresponding monitoring procedures as the preferable alternative.

REPORTS TO CONGRESS ON REFUGEE ASSISTANCE

Question: What is the status of the two reports to Congress required by the Refugee Assistance Amendments that were to be submitted to Congress by January 1, 1983?

Answer: The Office of Refugee Resettlement has completed its work in preparing these reports which are currently in departmental clearance. We expect that these reports will be provided to Congress very shortly.

Question: Were these reports contracted out to consultants or prepared by in-house staff?

Answer: The reports were prepared by in-house staff.

PARADYNE COMPUTER EQUIPMENT

Question: To what extent has this equipment been installed in SSA offices? How many units have been installed in how many offices? How long have these units been operational in the various offices?

Answer: As of April 19, 1983, 1,825 controllers, 1,825 printers, 525 card readers and 4,135 keystations have been installed by Paradyne in 1,400 SSA district and branch offices, 6 program service centers and 80 State disability determination service offices. Forty-two terminal configurations are scheduled for delivery, 122 are unscheduled. Depending on the installation

date--first installation occurred on June 30, 1981 and the last on February 25, 1983--equipment became operational upon acceptance and as such it was incremental throughout that period.

Question: What problems have these offices encountered with the equipment? How long have the problems been reported? Are things getting better or worse?

Answer: From the initial installation of the equipment, June 1981 to the present, 22 units out of a total of over 8,400 installed devices have been replaced by Paradyne because of excessive downtime equipment malfunction. From July 1981 until November 1982 problems were encountered with bringing the equipment to an operational state after equipment and/or software failures. During this period the Paradyne Corporation corrected many deficiencies at their expense and were assessed $280,000 in penalties by SSA. The problem of having to reinitiate the operating system of the terminals has been reduced from 2 per day to .4 per day. The uptime performance of the equipment is presently running at 98 percent. Ninety-five percent is required under the contract. Although the overall situation has improved, the reinitiation problem has not been completely resolved.

Question: Are these problems correctable? If so, how much will it cost, in terms of money? Will this equipment have to be totally replaced? How do these problems affect the substantial savings projected as a result of implementing local processing applications on these terminals?

Answer: Many of these problems identified to date have been corrected through improved problem determination, improved maintenance and management action at no cost to the government. As of the present, 22 units out of a total of over 8,400 installed have been replaced by Paradyne because of equipment malfunction and excessive downtime. Penalties incurred by Paradyne in terms of downtime credits to the government were approximately $280,000. Of the one problem remaining with respect to reinitiation of the system, it is correctable as evidenced by the drop-off in the percent of required system reinitiations. We do not at this time anticipate replacing the installed Paradyne terminals. Subsequent actions which may include replacement will be decided at a later date based upon the findings of the allegations against Paradyne. In the interim, SSA will not purchase any additional terminals. The local intelligence planned for the field offices can be (and will be) accomplished without upgrading the Paradyne terminal configuration. SSA will pursue an alternative technical approach, which will be less costly, yet provide the same capabilities. Since most of the applications will be implemented according to plan, any future workload savings will not be significantly affected by the technical approach adopted for local processing applications.

Question: According to the February 1982 SMP, the terminal replacement project encompassed by this contract is a key segment of the Data Communications Utility (DCU) Program--one of the four basic programs making up the SMP. How will these contracting problems effect the completion milestones and projected costs (1) for the DCU Program and (2) for SMP overall, as

reflected in the February 1982 SMP? Has the action required to correct these problems been reflected in the completion milestones and projected costs contained in the first annual SMP update? If so, what revisions have been made?.

Answer: SSA has completed the terminal replacement project through the acquisition of basic terminal quantities specified in the contract. The remainder of the Data Communications Utility Program is independent of the existing Paradyne terminals in the sense that they do not affect the backbone network or communication nodes other than the communications protocols necessary to interact with them. Some additional costs may be incurred as a result of not exercising the optional quantities clause of the Paradyne Contract for additional terminal equipment. The acquisition of additional terminal quantities would require a fully competitive procurement and would delay the terminal replacement plans in the program service centers by 18 to 30 months. Cost and schedule modifications to the SMP will be made after a more complete assessment of alternatives has been completed.

Question: Recent news media accounts of problems with this contract indicate that the device for providing terminal security is, in essence, totally worthless. Has this device been installed on the terminals, and if so, has the degree of security it is actually providing been evaluated? If so, what were the results? If not, what plans do you have for making such an evaluation?

Answer: The device you are asking about would provide data encryption capability, so that if a telecommunications transmission were intercepted, it would be unreadable. There is no current legislative or other mandate that such transmissions be encrypted. SSA included data encryption devices in its solicitation requirements only to ensure that the agency would have this capability if required by future security mandates. Only three devices were obtained with the first equipment for acceptance testing, and they were successfully tested. SSA will not be using the encryption devices, nor obtaining any more of them, in the foreseeable future.

UNNEGOTIATED CHECKS PROVISION OF SOCIAL SECURITY LEGISLATION

Question: Please provide for the record your estimate of the size of both the fiscal 1983 supplemental and fiscal 1984 appropriation, that will be necessary for the unnegotiated checks provisions of the Social Security legislation.

Answer: The Social Security Administration estimates that a $1.3 billion supplemental for fiscal 1983 and a $50 million budget amendment for 1984 will be necessary for the unnegotiated checks provision of the Social Security Amendments of 1983. In terms of appropriations for the Payments to Social Security Trust Funds account in 1984, this +$50 million will be more than offset by a large minus for pre-1957 military service credits, which, under the new legislation, are appropriated directly to the trust funds. Thus, there will be a negative budget amendment for this account. It also is important to note that SSA's estimates for

unnegotiated checks and military service credits have not yet been reviewed and approved by HHS or OMB.

Question: How would you estimate in advance the amounts needed for these quarterly transfers?

Answer: Section 152(a)(2) of the Social Security Amendments of 1983 requires that the Secretary of the Treasury credit the Trust Funds, on a monthly basis for the value of unnegotiated checks.

The initial transfer covering checks issued in the past is to occur the month after the month of enactment. Estimates for the initial transfer and monthly transfers thereafter were developed using data provided by the Treasury Department on the value of all unnegotiated checks and the length of time such checks have been outstanding. Future estimates will be based upon actual experience for the OASDI programs.

Question: Would this appropriation be to the Social Security Administration or the Treasury Department?

Answer: The law is not clear on this point, but we prefer that these funds be appropriated to SSA, the agency responsible for trust fund programs. Toward this end, a request for a 1983 supplemental and a 1984 budget amendment to have these funds appropriated to SSA are under review within the Administration. Unnegotiated checks would be a new activity within the Payments to the Trust Funds account. This account is specifically used to reimburse the trust funds for any payments owed to the Trust Funds by the General Funds of the Treasury. When these revisions are reviewed and approved by OMB we will forward them to the Committee.

PROGRESS ON SYSTEMS MODERNIZATION PLAN

Question: What progress have you made in implementing the 5-year Systems Modernization Plan you announced last March?

Answer: SSA is making good progress in implementing the Systems Modernization Plan and is well into the first 18-month survival period described in the Plan. Some of our recent accomplishments include:

1. Award of a Systems Engineering and Integration contract to provide continuous private sector management and technical engineering support to the plan until all aspects of the program are completed.

2. Continued enhancement of the Social Security Administration Data Acquisition and Response System--SSADARS--SSA's telecommunications network which links the Agency's field offices with the central computer facility. For example, two modern large scale processors were installed in February to replace the overloaded central processors.

3. Completion of a large-scale disk purchase to enable us to begin converting SSA's sequential tape files to direct access storage.

4. Initiating the Requirements Analysis project which provides for a comprehensive review of our functional requirements for developing new systems for SSA's programs.

5. Initiating the design of a new annual wage reporting system.

Question: What danger is there that the Social Security Administration will be able to make monthly payments on time in the near future, because your systems overhaul is only in the early stages?

Answer: SSA has made unprecedented progress during the first year of the 18 month "survival" period described in the modernization plan. The achievements during this first year ensure that the survival phase of the plan will be successfully completed. As a result, the risk of a disastrous systems failure has been greatly reduced and a more stable environment established for the agency's computer operations. The agency does not anticipate a repeat of the "close calls" experienced during last year's benefit conversion operations.

LONG RANGE PLANNING IN SOCIAL SECURITY

Question: What progress has Social Security made in establishing a comprehensive long-range planning process for the agency?

Answer: SSA's most significant achievement toward implementing an agency-wide planning process is the Systems Modernization Plan. Overhauling SSA's systems is our highest administrative priority. The Systems Modernization Plan also provides a framework for a more comprehensive planning process that will evolve from the current effort to implement the new Social Security legislation. SSA has set up a special group to oversee the planning for implementation of the new legislation, and a specific purpose of this effort is the evolution of an institutionalized, comprehensive planning process. As the process is developed, planning goals will be extended beyond immediate implementation dates and the scope of planning work will expand to include all major agency activities.

ADEQUATE SPACE FOR SOCIAL SECURITY OFFICES

Question: What progress is being made to provide adequate space for those Social Security offices which provide direct service to the public?

Answer: SSA's public contact offices are, for the most part, located in leased or trust-fund built space (some small contact stations are in rent free space). The problems with the acquisition/construction and maintenance of such space and deteriorating GSA services have been well documented and discussed for the past several years. To remedy the longstanding problems,

the Administrator of GSA and the Commissioner of SSA established space acquisition teams (SAT's)--composed of GSA, SSA and HHS personnel--to reduce the pending backlog of space requests during FY 1982. The SAT's made excellent progress in reducing the backlog of field office space requests, processing a significant portion of this workload, including many of the older, more difficult space actions. Of 451 cases pending on October 1, 1981, the SAT's processed all but 45. In addition, the teams processed 312 of 490 new cases received during FY 1982, leaving a pending caseload of 223 on September 30, 1982.

However, since the start of FY 1983, the situation has deteriorated. Funding problems combined with conflicting instructions to the GSA regional offices about implementation of the Administration's space utilization initiative have brought the acquisition of SSA space to a virtual standstill. The SAT's are now nonexistent in almost all regions. During the first quarter of FY 1983 under the provisions of the first Continuing Resolution (CR), GSA did not have available sufficient funds to cover known and anticipated leases for FY 1983. (SSA reimburses GSA for the cost of SSA's space. Even though SSA's budget for space may be adequate, GSA is limited by the amount of overall leasing funds appropriated to it.) As a result, GSA implemented tight, central office control over approvals for expansion space. The second CR provided some funding relief to GSA, but it was necessary for GSA to obtain approval from Congress to reprogram funds from other GSA accounts, including from renovation monies, in order to meet government leasing obligations.

The revised Federal Property Management Regulation (FPMR), published for comment in the Federal Register on March 8, 1983, but effective immediately, requires agencies to develop plans to reduce space utilization to a rate of 135 square feet per person or to reduce space utilization by a minimum of 10 percent by September 30, 1984. The space utilization initiative has been endorsed by the White House Cabinet Council for Management and Administration and has been made part of the "Reform '88" effort to improve Federal Government resource management. Even though the FPMR states that already approved Space Allocation Standards (SAS) are to remain in effect during the comment period on the new standards, GSA regional offices are returning requests that are in conflict with the new space utilization standards--that is, requests that exceed an average office space utilization rate of 135 square feet per person. Any exceptions must be negotiated with the GSA regional office and cleared through GSA central office. One problem with the new space utilization standard that we will work to resolve is the need to obtain recognition of special program responsibilities and operational requirements, such as SSA's need for reception areas in its field offices.

As a result of these problems, the backlog of pending SSA space requests has increased from 223 cases at the end of September 1982 to about 300 cases as of March 31, 1983, and unless GSA acts quickly to approve SSA's space utilization plan and to begin processing SSA space requests, we estimate that the backlog on September 30, 1983 will be approximately 500 cases. All this

information has been brought to the attention of GSA at the Associate Administrator level, and GSA has indicated that they will cooperate with us in helping to keep the SSA space activity on track.

STATE FLEXIBILITY IN ENERGY ASSISTANCE PROGRAMS

Question: In fiscal 1982 States acquired greater flexibility in the design and control of their own energy assistance programs. To what extent has this resulted in disbursing benefits more effectively?

Answer: The rationale for providing States with maximum flexibility to administer block grants is that the States are in the best position to judge the most effective allocation of resources among the needs of their citizens. The extent to which States have employed this flexibility indicates that they believe it does promote effective use of funds.

Question: Or, has this resulted in new problems specifically associated with State control?

Answer: We do not have any indication that there are new problems as a result of State control. The statute requires States to implement fund accounting and monitoring and to conduct an independent annual audit of the Low Income Home Energy Assistance Program (LIHEAP). Additionally, Federal compliance reviews and investigations of complaints have found no failures of States to expend LIHEAP funds substantially in accordance with the law.

Question: To what extent has the greater range of potential services increased the administrative burden on the States?

Answer: The Omnibus Budget Reconciliation Act of 1981 (OBRA) established the Low Income Home Energy Assistance Program for FY 1982 through FY 1984. In addition to heating, cooling and energy crisis assistance, which were authorized in FY 1981, OBRA authorized weatherization and low cost energy-related home repairs. States have had experience running the Low Income Weatherization Assistance program administered by the Department of Energy (DOE). Since most States spent LIHEAP funds for weatherization by using the same administrative systems in place for the DOE program, the resultant new administrative burden was minimal.

EXCHANGE OF DATA WITH STATES

Question: The Social Security Administration has obtained and verified benefit information from other Federal agencies to help minimize incorrect payments. Considering the large cost savings potential through more effective data exchanges, are you developing a program to obtain State and local data to compute benefits for all Social Security income maintenance programs?

Answer: Yes, we are working with States to increase the number of systems interfaces to verify information. The recent Social Security amendments provide that SSA will establish a

program for States to contract with HHS to supply information from official death certificates. The information will be confidential and exempt from Freedom of Information Act inquiries. We are also working with States to develop interfaces with other systems which provide information on worker's compensation and unemployment insurance benefits.

PERSONAL IDENTIFICATION NUMBER TECHNIQUES

Question: Since June 1978, when GAO first recommended that a personal identification number technique be incorporated into the telecommunications system, how many such cases have been detected and what sums were involved?

Answer: The following figures show the number of employee fraud cases that could be characterized as involving the agency's data communications networks and used transactions that would have been subject to a personal identification number (PIN) technique:

1978 - 5	$191,400
1979 - 3	106,790
1980 - 0	0,000
1981 - 2	95,000
1982 - 0	0,000
1983 - 1	13,000

It should be noted that there were other employee-perpetrated crimes during the period, but they involved activities other than fraudulent entry of data input transactions, such as stealing returned checks or cash refunds, or misappropriating interest funds. It should also be noted that there is no evidence that the use of the PIN would have prevented any of these incidents, although it is generally agreed that PIN's are a deterrent.

Question: Have any more such cases been uncovered since GAO's May 1982 report?

Answer: One case, involving $13,000, has been uncovered since 1982.

Question: As part of the Systems Modernization Plan what specific actions have been taken to incorporate the personal identification number technique into SSA's telecommunications system?

Answer: The Systems Modernization Plan lists improved security as one of its major objectives. Arriving at these security requirements is one of the responsibilities of the Systems Engineering and Integration contractor, and a separate subcontractor has been engaged for that purpose, as well as for establishing the requirements for financial and operational auditing and control. However, the modernization plan is primarily concerned with improving the data processing segment of SSA operational processes, and the personal identification technique referred to by GAO is not primarily a data processing problem.

Many experts agree that the term "computer fraud" is a misnomer for the most common form of such crime. These crimes are committed for the most part at the input source--that station in the work process where the input data is originated, its entry authorized, and the initial data input function (e.g., keying) performed. In SSA, this is far removed from the computer operation. By the time these transactions reach the computer application, they have passed through various manual operations, perhaps a review and authorization process, one or more various data entry processes SSA uses, and through one of our data communications networks. The PIN technique is intended to identify (and record the identity of) all the people who have contributed to or executed some function in this lengthy data input process, because all of the so-called computer fraud that has occurred in SSA is concentrated in that area. The PIN would act as a deterrent and an investigative tool. Unfortunately, upwards of 40,000 people are involved in those input processes, and we have yet to devise and establish a foolproof method of recording the actions and identity of each one.

SSA has had a contractor assisted effort underway since January 1982, to devise a method for identifying the people involved in this data input process. We do currently identify the authorizer of one of our vulnerable (but low volume) transactions: the immediate payment of critical cases. We are also now identifying, by PIN, almost all the keyers who use the SSA Data Acquisition and Reponse System (SSADARS) for data entry transactions. The remaining challenge is to devise a foolproof way to be sure we have identified originators, reviewers, and authorizers of data inputs--those steps that occur before the actual keying of the transaction--as well as covering data entry systems other than SSADARS. We plan to begin testing some approaches to these problems later this year as an outgrowth of the contractor assisted study mentioned above.

All these efforts will mesh with the Systems Modernization Plan, which must provide for handling, storing, and manipulating the personal identifying information generated by the personal identification techniques finally adopted. But the real challenge is ensuring that the security audit trail data (i.e., PIN) being entered is accurate and reliable.

MONTHLY REPORTING IN AFDC

Question: The Omnibus Budget Reconciliation Act of 1981 required State programs of Aid to Families with Dependent Children (AFDC) to adopt monthly reporting and to base recipients' benefits on income in a past month (retrospective monthly accounts). This change was urged as a means of reducing erroneous payments. How has the new requirement for monthly income reporting in the program Aid to Families with Dependent Children (AFDC) affected administrative costs and the accuracy of payments?

Answer: Monthly income reporting, along with retrospective budgeting and work programs have resulted in slightly higher administrative costs but far greater program savings. Further, flexibility is guaranteed in the monthly reporting system by the qualified granting of waivers to States that can demonstrate that

the system will not be cost-effective. The accuracy of payments is expected to improve but the system has not been in place long enough to statistically analyze the results.

AFDC STATE AND LOCAL ADMINISTRATIVE EXPENSES

Question: As a percentage of Aid to Families with Dependent Children benefit dollars, how much was spent by States and localities on administrative expenses in fiscal 1982?

Answer: Based on the most recent 1982 data the ratio of State and local administrative costs to AFDC benefit payments is 12.7 percent.

S&L Administrative Costs	$ 839,425,941	12.7%
AFDC Benefit	$6,614,029,775	

Question: Does this represent improvement over fiscal 1981?

Answer: Based on the most recent 1981 data the ratio of administrative costs to AFDC payments is 10.8 percent.

S&L Administrative Costs	$ 771,703,776	10.8%
AFDC Benefit Payments	$7,174,849,559	

As a result of changes enacted by the Omnibus Budget Reconciliation Act of 1981, the total amount of AFDC benefits dropped by 8 percent between FY 1981 and FY 1982. It is, therefore, misleading to compare the FY 1981 and FY 1982 ratios. Considering the scope and depth of changes in AFDC, the relatively minor increase (2 percent) in percentage of administrative costs with respect to total assistance payments reflects increasing efficiency in program administration and substantive program savings.

Question: What was the range in administrative costs among States?

Answer: There were a wide range of costs for administering the AFDC program throughout the United States. The lowest cost figures for 1982 were in the State of Wyoming at $625,848, the highest costs incurred were in California, $151,063,595.

Question: Has the Social Security Administration (SSA) completed development and testing of a cost allocation guide for State programs of Aid to Families with Dependent Children, as planned in 1982?

Answer: The Social Security Administration has completed a cost allocation guide for internal use. The Office of the Secretary of the Department of Health and Human Services is preparing cost allocation guidelines for the States which are presently in draft format.

Question: Which States deviate significantly from levels of performance considered desirable by SSA?

Answer: We do not now have a composite, overall level of performance for rating States' performance. What we do have is a report entitled "Profile of State Performance" which arrays State reported data on eleven indicators of performance. Although we have begun testing the possibility of establishing "desirable levels" for four of these indicators, we find that deficiencies in the comparability and reliability of the State reported data must be rectified before any meaningful norms can be established. In our continuing effort to improve the quality of the data, we will be awarding a contract in FY 1983 for the purpose of assessing these performance data and making recommendation for ways of improving these data to insure a greater degree of comparability and reliability. Even if we are able to improve the quality of these data, a methodology will have to be developed to adjust or otherwise interpret these data in terms of the differences among the individual States. At this point, we are not sure if this can be done. A separate contract is being planned to address this latter concern.

EXCESS FUEL ASSISTANCE FUNDS

Question: In the past, States have had large amounts of fuel assistance funds available after the heating season. What percent of fiscal 1983 appropriations for this program are expected to be transferred to other block grant programs or carried over to fiscal 1984?

Answer: In a February 1983 telephone survey, States reported that they have transferred or expect to transfer about $93 million from the Low Income Home Energy Asistance Program (LIHEAP) to other block grant programs in FY 1983. That represents about 5 percent of all funds appropriated for States for LIHEAP this year.

As yet, we do not know State plans for holding FY 1983 funds over to FY 1984. That information will be available after a telephone survey planned for this summer. States held about $180 million of FY 1982 funds over for use in FY 1983.

Question: Does the fact that this money was available after the heating season indicate that payments to the States were too high?

Answer: The Administration is proposing to reduce funding for the Low Income Home Energy Assistance Program (LIHEAP) from $1.975 billion to $1.3 billion. The history of carried over funds, tranfers out of the program, and the lack of transfers into the program indicate that reductions in LIHEAP funding could be made without necessarily leading to proportionate reductions in benefit levels or in the number of households assisted.

CORRECTNESS OF BLACK LUNG BENEFIT PAYMENTS

Question: What procedures do you have in place to ensure that Part B black lung benefits paid by the Social Security Administration are being properly reduced when the beneficiary is also in receipt of payments under a State worker's compensation law or other disability insurance system?

Answer: The black lung program is a small part of SSA's overall administrative operation and is not fully automated. Thus, we depend to a large extent on manual operations to correctly pay benefits. In that respect, we also depend on beneficiary reporting of receipt of worker's compensation or other such payments to reduce correctly the Part B benefit. The application for benefits includes a question on such payments and a reminder to notify SSA of entitlement to or a change in the amount of such payments. In addition, SSA cross-refers its Social Security and black lung files in order to assure that events affecting Social Security benefits are also reflected in the black lung payment.

Question: Is regular computerized cross-checking with these other benefit programs employed?

Answer: SSA has no ongoing computerized matching with State worker's compensation records or other outside disability programs. However, we do have controls in place to ensure that actions taken on a Social Security claim (such as offset or earnings reductions) are also taken on the black lung claim. When the miner is also entitled to Social Security disability benefits, the folders are located together. In addition, SSA's case control system and Social Security benefit records show if a black lung claim is also involved. When local Social Security offices input automated actions on the Social Security record, they are also required to send the information to central office for association and manual action on the black lung claim.

Question: What procedures do you have in place to ensure that Part B black lung benefits paid by the Social Security Administration are being properly reduced when the beneficiary has excess earnings that would reduce a Social Security benefit?

Answer: Black lung beneficiaries are required to report to SSA any earnings which could cause a reduction in benefits. Beneficiaries who have previously reported earnings or been subject to reduction of benefits due to earnings are sent annual reports to provide SSA with actual and estimated earnings. In addition, SSA cross-refers its Social Security and black lung files in order to assure that earnings reported in the title II folder are also reflected in the black lung payment.

Question: Do you regularly cross-check with earnings reported through the Social Security system or through the unemployment insurance system?

Answer: In 1981, the Internal Revenue Service (IRS) ruled that the Tax Reform Act of 1976 prohibited SSA from using tax return data in administering the black lung program. Thus, SSA cannot verify the amount of earnings reported by beneficiaries or detect unreported earnings by examining tax return data, unless prior written consent is obtained. SSA has no cross-checking capabilities with State unemployment compensation systems.

Question: To what extent are Part B black lung benefits paid by the Social Security Administration reduced because beneficiaries receive other payments, such as worker's

compensation for black lung or have excess earnings that would reduce a Social Security retirement benefit?

Answer: Part B benefits are reduced dollar-for-dollar for worker's compensation payments received because of disability due to pneumoconiosis. For excess earnings, black lung benefits are reduced by $1 for each $2 that earnings exceed the annual limit. In 1983, the limits are $4,920 for beneficiaries under age 65, and $6,600 for those 65 and over (up to age 70).

Question: In what proportion of the nearly 400,000 Part B cases are these reductions applied?

Answer: In March 1983, approximately 350,000 beneficiaries (miners, dependents and survivors) were receiving Part B black lung benefits. Of these, fewer than 700 were in offset due to receipt of a worker's compensation payment. In addition, about 200 had some reduction in benefits due to excess earnings.

Question: How are these cases identified?

Answer: Cases in which reductions should be applied due to worker's compensation or earnings are identified by reports from the beneficiary, by the history of the black lung file itself (prior reductions), or from information in the Social Security file (if the beneficiary is also entitled to those benefits).

Question: How successful have debt collection efforts been to recoup Part B Black Lung benefits that should not have been paid because a reduction should have been applied for receipt of other disability payments or earnings?

Answer: Specific data are not available to indicate how successful we are in recovering black lung overpayments occurring as a result of SSA discovering too late that the beneficiary also received other disability payments or earnings. Usually such findings reduce (rather than eliminate) monthly benefits. Thus, we are able to recover the overpayments in installments over periods of time, depending on the individual's ability to repay. During FY 1982, about 80 percent of all types of black lung overpayments cleared were collected. Most of this was the result of check adjustments.

INVENTORY OF STATE AFDC COMPUTER SYSTEMS

Question: The Federal Government is funding automatic data processing systems under the AFDC and Child Support Enforcement programs. Has the Social Security Administration prepared a comprehensive inventory of State ADP systems to determine:

--existing State systems already paid for by the Federal Government and their use?

--the planned systems for each State, their anticipated costs and use?

--the extent to which there is duplication of funding from various agencies?

Answer: Yes, the Social Security Administration (SSA) has compiled a complete State Systems Profile which contains a variety of information including general information on the State AFDC program and the supporting AFDC management information systems (MIS) and the data processing environment. The profiles also include specific information on how the State's MIS compares with the specific requirements in the guidelines for the Family Assistance Management Information System (FAMIS) which is funded at 90 percent Federal financial participation.

Anticipated costs and use of State ADP systems are required to be addressed in an Advance Planning Document (APD) whenever a State applies for Federal matching funds for either software development or hardware. The APD also addresses the percentage of the system and its cost which are attributable to each of the Federal programs involved. The HHS Office of the Assistant Secretary for Management and Budget coordinates State requests which involve more than one program, not only within the Department (AFDC, CSE and Medicaid) but also with the Department of Agriculture for the Food Stamp program. This precludes duplicated funding.

Regarding the Office of Child Support Enforcement, we have an inventory of State and local systems approved for Federal funding so that such systems are not duplicated in the future.

Question: Under the Omnibus Budget Reconciliation Act of 1981, Public Law 97-35, AFDC recipients are required to apply for advanced payments of any earned income tax credits they may be eligible for rather than receiving year end lump sum payments. Has the SSA determined the benefits to recipients and the administrative feasibility and cost effectiveness of this provision? If not, why not? If so, what are the results?

Answer: This provision does not require recipients to apply for advance earned income credits. It only requires States to count as income during the year the amount of earned income credits which individuals are expected to be eligible to receive at the end of the tax year.

Originally, we estimated that savings to the AFDC program from this provision would exceed the costs by about $45 million per year. We know that our estimates of the overall savings resulting from the Omnibus Budget Reconciliation Act of 1981 (OBRA) were quite accurate, but it is very difficult to separate out the savings attributable to individual provisions. Also the provision was not designed specifically to benefit recipients; it was designed to ensure that sources of income and support which are available to recipients are counted in determining eligibility and the amount of assistance.

To ease administration of the provision, we are developing a technical assistance package for the States.

Additionally, IRS has informed us that in-kind benefits must be considered in determining what proportion of household support

is provided by the wage earner. When in-kind benefits are counted, the proportion of AFDC recipients affected by this provision could be reduced significantly.

PRIVACY PROTECTION AND SYSTEMS SECURITY IN SSA SYSTEMS PLAN

Question: GAO's May 1982 report identified the Systems Modernization Plan's provisions for privacy protection and systems security as the area needing the most improvement, primarily because the plan lacked details on this subject. What changes/additions if any, have been made in this area?

Answer: In response to GAO's concerns SSA has expanded upon its security and privacy tasks within the SMP. Integration concentrator expertise has been obtained to establish a Control and Audit Group with the following responsibilities: Assessing the adequacy of control and audit features in the programmatic systems, tracing the flow of recipient information through the systems, testing the quality of data in the files, reviewing GAO recommendations for control and audit improvements and reviewing GAO's method of simultaneous/parallel processing for applicability to title II (RSDI) systems and others. The purpose of these control and audit activities is to develop and implement improvements in the accuracy of data flowing into and out of the systems by providing the control and audit capabilities that should have been included already. The control and audit group will perform these activities and provide the expertise necessary for SSA to implement state-of-the-art control and audit techniques. The control and audit group has prepared a preliminary design for a test environment to provide a basis for improvement in the integrity and control of SSA's programmatic systems. This expanded effort within the SMP is designed to correct past deficiencies by making control and audit issues an integral part of the systems improvement and development process and by providing an environment which supports and encourages continuing in-depth testing of new and existing systems.

AFDC ADMINISTRATIVE COSTS IN PUERTO RICO AND TERRITORIES

Question: The Social Security Act limits total Federal funding for cash welfare benefits and their administration to fixed amounts in Puerto Rico, the Virgin Islands and Guam. In the 50 States and the District of Columbia, Federal funding is varying percentage share of actual costs, 50 percent in the case of administration. How do administrative costs for Aid to Families with Dependent Children in Puerto Rico, the Virgin Islands and Guam, where a ceiling is applied to Federal matching funds for cash aid and its administration, compare with those in the U.S., where no such ceiling is imposed?

Answer: Administrative costs for AFDC in Puerto Rico, the Virgin Islands and Guam are roughly proportionate to the national average. The ratio of administrative costs with respect to

Assistance Payments in the territories is within a few percentage points of the national average (12.7 percent). Specifically in FY 1982,

Guam		
Administrative Costs	295,985	10.5%
AFDC Benefit Payments	2,809,827	
Puerto Rico		
Administrative Costs	6,248,015	13.1%
AFDC Benefit Payments	47,593,922	
Virgin Islands		
Administrative Costs	173,260	8.5%
AFDC Benefit Payments	2,035,268	

NOTE: All calculations are based on the most recent, corrected FY 1982 data.

SSI STATE SUPPLEMENTATION ERRORS

Question: What percentage of federally-administered State supplementary dollars paid to ineligible persons?

Answer: Based upon information compiled from the supplemental security income (SSI) quality assurance sample for the October 1980-March 1981 period, 4.1 percent of federally-administered State supplementary dollars are paid to ineligible persons. In addition, quality assurance data indicate 1.9 percent of supplementary dollars represent overpayments to recipients who retain SSI eligibility.

Question: What percentages are paid in the correct amount?

Answer: According to the same data source, 94 percent of all payments are paid correctly.

Question: How do these rates compare with target rates you set for States to meet in the programs of Aid to Families with Dependent Children and Medicaid?

Answer: In action on the FY 1979 Supplemental Appropriation Act and the Michel Amendment to the FY 1980 appropriation bill, the Congress directed that States reduce AFDC error rates to 4 percent by September 30, 1982 and provided interim target error rates beginning with FY 1981 reporting periods. The Tax Equity and Fiscal Responsibility Act of 1982 specified that States should achieve a target error rate of 4 percent in FY 1983 and 3 percent in subsequent years. The AFDC error rate for the most recent period for which actual data is available (FY 1981) was 7.7 percent. For the Medicaid program, the Tax Equity and Fiscal Responsibility Act abolished the impact of the Michel Amendment error rate targets for FY 1981 and 1982. The target for the second half of FY 1983 is 3 percent, excluding technical errors. The most recent actual error rate for the Medicaid program is 3.8 percent for FY 1981.

Question: What are you doing to improve the accuracy?

Answer: Our plans to improve the accuracy of federally-administered State supplementary payments are allied to our other payment error reduction efforts, i.e., program simplification, computer matches, expanded public information activity, improved forms/interviewing.

MONTHLY REPORTING IN SSI PROGRAM

Question: For what kinds of recipients of supplemental security income (SSI) has the Social Security Administration (SSA) adopted mandatory monthly reporting of circumstances relevant to benefit entitlement?

Answer: SSA has not identified whether there are groups of recipients for whom mandatory monthly reporting would be a cost-effective procedure. Therefore, mandatory reporting procedures have not been adopted.

Question: What combinations of reporting and income accounting procedures show promise of increasing the accuracy of payments? At what extra administrative cost?

Answer: We do not believe that major changes to our current retrospective monthly accounting (RMA) system will increase program accuracy. We see the road to improve payment accuracy as follows: (1) program simplification to provide program requirements with which recipients can more readily comply at lower program cost; (2) computer interfaces to uncover unreported income and assets; (3) more intensive public information activities which stress recipient reporting requirements; and (4) more effective forms/interviewing. We are not able to judge at this time what these procedures will cost.

Question: What would be the impact on recipients?

Answer: Considering that the circumstances of SSI recipients do not usually change very much and that the SSI population is composed of the elderly and disabled, the need to complete monthly reports under a mandatory reporting procedure would be very confusing and unnecessarily burdensome for many SSI recipients.

COMPLETION OF CERTAIN SYSTEMS MODERNIZATION ACTIONS

Question: Concerning the current status of key modernization actions that were incomplete at the time of GAO's May 1982 report, has Social Security appointed a Deputy Commissioner for Systems?

Answer: Yes, the Deputy Commissioner for Systems is Marshall S. Mandell.

Question: Has Social Security completed the realignment of its organizational structure for Systems?

Answer: The realigned organizational structure for Systems was formally announced in the Federal Register on January 4, 1983 (pages 337-343). This action officially established the key

organizational components required to accomplish the Systems Modernization Plan (SMP); the Deputy Commissioner for Systems, the Office of System Requirements (OSR), the Office of System Integration (OSI), and the Office of System Operations (OSO), and their subordinate offices and staffs. However, SSA had been informally operating under this basic organizational configuration since the middle of 1982. The steps needed to complete the realignment at the division level and below are well underway, with Federal Register publication of this level of organizational detail expected within the next 2 months.

Question: How does the realigned structure differ from the prior structure?

Answer: In the prior organization, systems maintenance/operations components and systems design development components were merged within the Office of Systems under the direction of the same Associate Commissioner. The Systems Modernization Plan realignment separates ongoing operation and maintenance of existing systems (located in the Office of Systems Operations) from systems development and engineering (located in the Office of System Integration) to achieve the concerted effort needed to complete the design and implementation of the new system and to avoid disruption in the operation of the existing system. It also established the Office of System Requirements (OSR), which provides the essential link between SSA's overall purposes and its data processing capabilities. OSR is responsible for identifying and developing user-oriented systems requirements that are stated clearly and in terms understandable to both users and systems analysts. Finally, the plan assures unified direction, high-level executive attention, and focused responsibility and accountability for accomplishment of agency-wide systems modernization objectives through the establishment of a Deputy Commissioner for Systems.

Question: Has Social Security hired an integration contractor, and if so who and has he begun work?

Answer: On December 8, 1982 SSA hired the Electronic Data Systems Federal Corporation as its systems engineering and integration contractor. This company has begun work.

MONTHLY DATA ON AFDC PROGRAM

Question: What plans has the Social Security Administration for speeding up the very tardy publication of monthly data on a State-by-State basis about recipients and benefits in the program of Aid to Families with Dependent Children?

Answer: Through 1979 SSA collected recipient characteristics in AFDC every 2 years. The data itself was extracted by case workers from over 20,000 cases.

Currently SSA collects AFDC recipient characteristics as part of the quality control process. This avoids duplicate review saving State and Federal staff time and expense. The data are more current, since they are updated monthly rather than every 2 years and more reliable because of the larger quality control sample.

In the interim period between the 1979 survey and availability of data from the new collection method, OFA has had recipient characteristics extracted from over 12,000 cases in payment for May 1981 and May 1982. This data will be available within the next few months.

USE OF CONTRACTORS TO OVERSEE AFDC PROGRAM

Question: For which of its duties related to overseeing the program of Aid to Families with Dependent Children does the Social Security Administration plan to use contractors in fiscal 1983 and what is the estimated cost of these contracts?

Answer: At present we have actually awarded only $105,000 in extensions of 1982 contracts. We have requested consultant services (from suppliers other than States or agencies of the States) on a variety of projects, and expect to award a total of approximately $1,895,000 in consultant services by the end of FY 1983. Of that total, $920,000 will be from Work Incentive (WIN) program monies transferred to SSA from the Office of Human Development Services. The major contracts are: WIN demonstration evaluation and validation of Federal demonstration data; monthly reporting exemption evaluation; measurement of the effectiveness of corrective actions; job search training (WIN); and, AFDC staff training (WIN).

Question: What research methods is the Social Security Administration using to evaluate the results of major changes made by Congress in the program of Aid to Families with Dependent Children?

Answer: We are using a variety of research tools including case studies, interviews, automated statistical and budgetary analysis at both the regional and Federal levels to ascertain the exact effects on the AFDC program throughout the United States. For example, SSA awarded a contract in September 1982 to Research Triangle Institute of North Carolina to design and conduct an independent evaluation of the most significant and controversial changes, namely those amendments that affected the treatment of recipients' income and work expenses. Two major surveys have been employed.

The first is a survey of case records of almost 2,000 cases, most of whom reported earnings, in 40 counties across the country. The cases were drawn from two reference months, September 1981 and 1 year earlier, September 1980, and were tracked for 1 year beyond each reference month for month-to-month changes in eligibility and benefit status. This information was supplemented by a follow-up interview with 200 individuals who were made ineligible and did not return to AFDC rolls.

The result has been a unique longitudinal data base describing the household composition and income sources of AFDC families over a 1- to 2-year period; it will enable us for the first time to learn at a national level about the normal dynamics of case openings and closings and to assess the affect of the work-related AFDC amendments on recidivism. Moreover, this study, the results of which are expected in April, will provide us with

more definitive measures of the impact of these new policies on the work status and earnings levels of eligible and ineligible families, on the distribtion of resources among low income families and finally on the cost of providing AFDC.

A second study which is underway is a comparison of recipient characteristics of families receiving AFDC 6 months before the changes resulting from the Omnibus Budget Reconciliation Act of 1981 (OBRA) with families on the rolls 6 months after the October 1 implementation date. Detailed information on household composition, reported resources and income, WIN status and other eligibility factors has been abstracted from quality control review schedules and worksheets for a national sample of 7,000 cases in each period. This effort will provide us with national indicators of how the caseload has changed from the pre- to post-OBRA period, as well as a recent data base to evaluate further policy proposals. Preliminary results are expected this spring.

WORK INCENTIVE DEMONSTRATION PROGRAMS

Question: What States have chosen to establish Work Incentive (WIN) demonstration programs, under the direction of their welfare agencies, as an alternative to the regular WIN program?

Answer: Currently 18 States are operating WIN demonstration programs. They are:

Arizona	Maine	New Jersey	Texas
Arkansas	Maryland	Oklahoma	Virginia
Delaware	Massachusetts	Oregon	West Virginia
Florida	Michigan	Pennsylvania	
Illinois	Nebraska	South Dakota	

Question: What are the tentative conclusions from these experiments in single agency operation of WIN?

Answer: The authorizing legislation for the WIN demonstration program calls for evaluations after the first and third years of operation, and the Office of Family Assistance, Social Security Administration, Department of Health and Human Services has been delegated responsibility for carrying out these evaluations. It is our understanding that at this time there are not sufficient data available on which to base an assessment of WIN demonstration program effectiveness.

REPATRIATION PROGRAM

Question: Why did the estimated average cost of care for repatriated citizens who were mentally ill exceed $65,000 per patient-year in fiscal 1982? What is the estimate for FY 1983?

Answer: The budget estimates an average cost of $62,500 per patient year of care in FY 1983. This estimate is based on the cost of care at St. Elizabeth's hospital in Washington where most of the patients covered by this program are cared for.

We are now analyzing actual 1982 cost per patient year which appears to be significantly lower than our original estimates.

Question: How many mentally ill citizens did the repatriate program help in fiscal 1982? How many other repatriated citizens, those destitute or physically ill?

Answer: During FY 1982, 16 patient years of care were provided to mentally ill nationals and 447 other repatriated citizens were assisted through the repatriate program.

Question: On the average, what percentage of U.S. citizens who receive temporary assistance in returning home from abroad because of destitution or illness later repay the aid? What measures are taken to recoup the cost of this aid?

Answer: In FY 1982 and prior years less than 1 percent of the assistance provided has been repaid. In FY 1983 the Social Security Administration has been developing a systematic repatriation billing program which is expected to be operational by June 1983. Under this system, repatriates will be required to sign a repayment agreement before services are provided and a series of collection letters has been developed for automated issuance on a monthly basis. This increased effort toward collection will improve the rate of repayments received. Objective criteria will be used to waive repayment and in cases of refusal to repay, SSA will refer them for further action to appropriate agencies.

EMERGENCY ASSISTANCE PROGRAM

Question: What impact did the 1982 recession have on caseloads and benefit amounts in the Emergency Assistance program?

Answer: We actually experienced a decrease at the national level in expenditures for the period of 1981-1982 ($58,826,000 to $45,417,000). We do not have data to explain the reason for the decrease in a time when unemployment is high. Further estimates indicate 1983 and 1984 expenditures are estimated at $50,700,000 and $52,500,000 respectively. It is interesting to note that the projected expenditures for 1984 are below actual expenditures in 1981 by over $6,000,000.

Question: Which States have not implemented an Emergency Assistance program as an adjunct to their Aid to Families with Dependent Children program?

Answer: In FY 1982, the following States did not have an Emergency Assistance program:

Alabama	Maine
Alaska	Mississippi
Arizona	Missouri
Colorado	Nevada
Connecticut	New Hampshire
Florida	New Mexico
Georgia	North Carolina
Guam	North Dakota
Hawaii	Rhode Island
Idaho	South Carolina
Indiana	South Dakota
Iowa	Tennessee
Kentucky	Texas
Louisiana	Utah

In FY 1983, the Virgin Islands will drop its Emergency Assistance program.

AFDC DRAWDOWN IN FY 1982

Question: How much money from the fiscal 1983 appropriations for the program of Aid to Families with Dependent Children (AFDC) was drawn down for use in fiscal 1982?

Answer: We actually drew down $631,978,000 from FY 1983 appropriations for use in FY 1982.

Question: What part of the total was needed because fiscal 1982 savings anticipated from passage of the Budget Reconciliation Act of 1981 were smaller than expected? What part was due to the failure of Congress to enact new budget cuts with fiscal 1982 effect?

Answer: When we presented our FY 1983 budget to the Congress, we estimated that we would need to borrow $728.7 million from FY 1983 to meet FY 1982 needs. This included anticipated savings of $201 million from proposed legislation; without the legislation we expected to borrow $929.7 million. Part of the estimated shortfall, about $300 million, was attributed to a revised estimate of first year savings from the Omnibus Budget Reconciliation Act (OBRA) of 1981 reflecting some delays in implementation by the States. A larger part, about $400 million, was based on the levels of unemployment and inflation then anticipated by the Administration. Compared to our estimated drawdown of $929.7 million absent legislation, the actual drawdown of $632 million was almost $300 million less. We do not know with a high degree of certainty why the actual costs were so low, but we believe that the factors may include: a lower rate of inflation, a lower level of erroneous payments and a higher level of savings from OBRA provisions.

CHILD SUPPORT COLLECTIONS

Question: How much money in child support obligations is expected to be collected from absent parents in fiscal 1984 under the Child Support Enforcement program? From how many parents?

Answer: For FY 1984, an estimated $923 million will be collected on behalf of AFDC recipients under current law. This represents collections from 945,000 absent parents in the AFDC program.

Although not reflected in the budget, collections on behalf of families not in receipt of AFDC will exceed $1 billion in FY 1984 based on recent experience.

Question: What are the results of the new program to collect delinquent support owed on behalf of Aid to Families with Dependent Children by subtraction from Federal income tax refunds?

Answer: The Federal income tax offset program was first operative for tax year 1981 income tax returns. The program resulted in AFDC collections of nearly $169 million.

Question: How much money did the Federal Government lose on child support operations in fiscal 1982? Why? How much did the States gain?

Answer: Total AFDC collections for 1982 were $793 million with total administrative costs of $587 million for a total savings to the taxpayer of $191 million. This latter figure is divided between the Federal and State Governments according to the program financing structure now in the law; the $191 million savings to the taxpayer is composed of two distinct parts, a loss to the Federal Government of $133 million and a savings to the State Governments of $324 million. This occurs because the State share of AFDC child support collections, including incentive payments, equaled 59 percent while their share of total costs equaled 25 percent.

Question: What is the Office of Child Support Enforcement doing to promote more efficient collection programs by States and localities?

Answer: Under current law, OCSE has several initiatives designed to foster a more effective and efficient child support enforcement program. As mentioned before, in the 1981 tax year we implemented with IRS a Federal tax offset procedure in which Federal income tax refunds are intercepted for past due child support on behalf of AFDC recipients. We have begun an urban assistance initiative in which OCSE and contractor personnel provide technical expertise to major urban areas tailored to improve their program performance. Such efforts are now progressing in six major urban areas across the country.

Additional efforts are directed to improvement of management and program effectiveness through studies which analyze program operations and make specific recommendations for remedial action. Special, preferential funding and technical help

encourages State and local automation of recordkeeping and other program activities. Worthwhile program techniques are disseminated through various OCSE publications, including a monthly newsletter. OCSE also supports, under contract, training for State and local child support enforcement personnel ranging from front-line interviewers to managers and members of the judiciary. And, technical expertise is extended to States in the adoption of beneficial legislation through an agreement with the National Conference of State Legislatures.

A continuing financial management oversight and auditing function also plays a key role in promoting a stronger child support program. And, the orientation of audit activities is being refocused to much more of a performance or results kind of approach rather than the preponderent emphasis on program compliance that has prevailed since 1975.

While more undoubtedly can be accomplished under present law, OCSE believes that enactment of the Administration's legislative proposals will facilitate and stimulate a much stronger child support program.

Question: What is the range among States in the cost of collecting one dollar of child support?

Answer: In FY 1982, the 10 best States collected on the average $2.47 of AFDC collections for every dollar spent, while the 10 worst States collected only 49 cents for each dollar spent. The range for all States was from $.37 per dollar to $3.75 per dollar, with a national average of $1.33. Total collections, both AFDC and non-AFDC per administrative dollar spent in FY 1982 ranged from $.63 to $2.26 per dollar, with an average of $2.99.

REVENUES FROM WINDFALL PROFIT TAX

Question: According to the Crude Oil Windfall Profit Tax of 1980, 25 percent of expected Windfall Tax revenues were expected to be earmarked for low-income energy assistance. Is the current funding level in accord with this? If not, why not?

Answer: The Crude Oil Windfall Profit Tax of 1980 (section 102) contains a description of how Congress felt revenues from the tax should be distributed. The breakdown was:

Income tax reduction	60 percent
Low-income assistance	25 percent
Energy and transportation programs	15 percent

However, Congress did not establish a mechanism to allocate Windfall Profit Tax receipts to specific programs. Rather, these funds are considered as general revenues and are subject to the normal appropriation process. No program is funded out of earmarked Windfall Profit Tax receipts.

Also, while the energy assistance program was authorized for FY 1981 by title III of the Crude Oil Windfall Profit Tax Act of 1980, this authority has been repealed. The authority for the Low

Income Home Energy Assistance Program is now title XXVI of the Omnibus Budget Reconciliation Act of 1981.

Projected revenues for 1984 from the Crude Oil Windfall Profit Tax Act of 1981 are $12.2 billion, projected net revenues are $6.4 billion.

FOCUS OF FUNDING IN ENERGY ASSISTANCE PROGRAM

Question: To what extent does the expansion of energy assistance services to include weatherization and increased cooling assistance fragment the funding and thus dilute the overall effectiveness of the program?

Answer: States have focussed Low Income Home Energy Assistance Program (LIHEAP) funds on heating assistance needs. About two-thirds of the funds available to States for FY 1983 will be used for direct heating assistance. Another 8 percent will be used for energy crisis assistance, most of which is for heating crisis. Another 11 percent is to be used for weatherization, in order to reduce long term heating costs and the need for heating assistance in future years.

Question: Would the program be better served by determining its most effective aspect and focusing funds in that area?

The States themselves, rather than the Federal Government, are in the best position to determine the relative needs of their citizens for heating assistance or for cooling assistance, and to determine the best balance of meeting immediate fuel assistance needs and reducing those needs by weatherization measures. The overall effectiveness of a block grant program cannot be measured accurately without taking these State perspectives into account. We support State flexibility to allocate energy assistance resources among these purposes.

While States should not be restricted further in the uses they may make of Low Income Home Energy Assistance Program (LIHEAP) funds, we will propose a change to the distribution of LIHEAP funds among the States which will send a greater portion of available funds to States with the greatest need for heating assistance. However, we expect that some States will continue to allocate a portion of their funds to provide assistance with cooling costs to low income households at risk from extremes of summer heat.

INCREASED DEMAND FOR FUEL ASSISTANCE

Question: To what extent has the demand increased for fuel assistance under the Low Income Energy Assistance program?

Answer: The table below shows the variation in the numbers of households assisted by States over the last 3 years. The FY 1983 figures are estimates based upon a telephone survey performed in February. In the past, mid-winter estimates of the total numbers of households to be served have proven to be too high.

Caution should be exercised in using these numbers as measures of program demand. Between one-third and one-half of households receiving energy assistance receive it automatically, without filing an application, or by returning a short questionnaire mailed automatically to their homes. While demand for the program might be reflected by the numbers of households who come in to State offices and apply for assistance, demand is not reflected so clearly when households receive the assistance more or less automatically.

	FY 1981	FY 1982	FY 1983
Heating Assistance	7.0 million	6.0 million	6.6 million
Crisis Assistance	included in heating assistance	680,000 (about 70% also receive heating assistance)	875,000 (about 70% also receive heating assistance)
Cooling Assistance	392,000	1.1 million	Not available
Weatherization	Not an authorized use	440,000	143,000 (does not include estimates for 7 States which last year reported serving 315,000 households)

Question: Is it growing due to increased unemployment? Due to inflation? Due to greater public awareness to the program?

Answer: In our February 1983, telephone survey States estimated they would provide heating assistance to about 600,000, or 10 percent more households in FY 1983 than they reported serving in FY 1982. States also estimated they would assist 190,000 more households through their crisis assistance program. Informally, some States have attributed this increase to higher unemployment levels, higher energy costs, the expectation that the winter of 1982/83 would be colder than normal, and greater public awareness of the program.

It is important to note, however, that these figures are estimates of the number of households States expect to serve in FY 1983. States have, historically, overestimated the number of households actually served. In March 1982, we conducted a telephone survey in which we asked States how many households they expected to serve. They estimated they would serve about 6.2 million households. Based on States' end-of-year reports, they actually served about 6.0 million households. We expect the actual increase in the number of households served in FY 1983 to be smaller than indicated by the estimates collected in February.

All Low Income Home Energy Assistance Program (LIHEAP) grantees have flexibility to adapt their programs to changing needs of their citizens by adjusting eligibility levels and benefit amount to best utilize resources. States also have the option to increase LIHEAP funding by transferring funds into the energy block grant fron the social services and community services block grants. No State has found it necessary to increase LIHEAP funding by this method. Actually most States have chosen to decrease LIHEAP funding by transferring funds out of LIHEAP to other block grants.

Question: Has the Administration made any recent study of the need for this type of assistance, especially regarding the numbers of people to be served and where the need is located? Is so, what were the findings?

Answer: Our August 1982 report to Congress on the FY 1981 energy assistance program included information on typical energy costs borne by low income households in different regions. We will update and refine that information for our report on the FY 1982 program.

The typical household that receives low income home energy assistance has an income well below the Federal eligibility level. The greatest energy need for assistance is found in those States with the largest low income populations and the highest average home heating costs.

EFFECT OF 1981 RECONCILIATION ACT ON AFDC RECIPIENTS

Question: In October 1981, the month of initial effect of some provisions of the 1981 law, the number of AFDC recipients dipped below 11 million for the first time in more than a year.

By June 1982, overall enrollment has slipped to 10.2 million, down 8 percent from the year-earlier count. That month the number of persons receiving AFDC because of the absence, death or incapacity of a parent (chiefly children in one-parent families and their mothers) fell to 9.2 million, the smallest such count since spring of 1971. However, the number receiving aid on grounds of the unemployment of a parent was near-record high, totaling 0.9 million.

What part did the Omnibus Budget Reconciliation Act of 1981 play in reducing, to the lowest point in more than a decade, the number of persons in one-parent families who are enrolled in the program of Aid to Families with Dependent Children (AFDC)?

Answer: By more equitably counting the income and resources available to AFDC families the 1981 Omnibus Budget Reconciliation Act (OBRA) made an estimated 400,000 assistance units ineligible. Based on the current average unit size about 1.1 million recipients were made ineligible, mostly single parent family units.

However, despite a general growth in caseload, the number of recipients has been declining independent of OBRA. In addition to the decline in fiscal 1982 there were declines in the total number

of recipients to new lows for the last decade in 1977, 1978 and 1979. These declines occurred despite rising expenditures in each year and in the absence of major policy changes. This is attributable to the fact that the average number of people in each assistance unit has been growing smaller. In fiscal 1974 the average number of recipients per case was 3.4 while in fiscal 1982 it was 2.8, a 16 percent decline.

Question: What has happened to employment rates for recipient mothers under the revised Aid to Families with Dependent Children (AFDC) law, which increased work requirements but repealed financial rewards for sustained work?

Answer: Based on our computer forecasting model, it was projected that the employment rate for AFDC mothers would be approximately halved as a result of the lower eligibility ceilings introduced by the Omnibus Budget Reconciliation Act of 1981 (OBRA). We are studying this issue as part of our evaluation of the effects of OBRA, and data to answer the question directly will be available by early May.

Question: How many AFDC mothers who formerly worked have quit their jobs and thus moved from partial to total dependence on welfare?

Answer: There is no national data on the number of formerly employed AFDC recipients who lost their income and returned to welfare as a result of quitting as distinguished from loss of a job. Data currently available from State studies on the effects of the income-related OBRA changes indicate that only about 10 percent of cases closed due to excess earnings are on the welfare rolls at a late date. This includes individuals who return with earnings and therefore cannot be considered totally dependent. For example:

	Reason for Closure	Rate of Return
New Jersey	Income-related OBRA	13.9% by 10/82
Massachusetts	All OBRA	10.8% by 8/82
Illinois	Income-related OBRA	9.4% by 6/82
Los Angeles	Income-related OBRA	10.3% by 6/82

There is also some evidence supported by Sheldon H. Danzinger of the University of Wisconsin's Institute for Research and Poverty and by Richard P. Nathan of Princeton University's Urban and Regional Research Center that the 10 percent rate of return reflects the normal rate at which former recipients return to welfare after an income loss. Hence there are currently no data to support the theory that there has been any change in former recipients' work behavior in response to the income-related 1981 AFDC amendments. By early May we will have data available from a

SSI HOLD-HARMLESS

Question: What amounts are to be paid to Wisconsin and Hawaii for hold-harmless payments under the Supplemental Security

Income (SSI) program in fiscal 1984, the last year of such funding?

Answer: We project that for FY 1984 the split between the two States that still receive hold-harmless payments will be $10,000 for Hawaii and $4,990,000 for Wisconsin.

Question: To what States has the Federal Government made hold-harmless payments over the years? What amounts did each State receive?

Answer: From FY 1974 through FY 1976 there were six States that received payments for hold-harmless. They were California, Nevada, New York, Hawaii, Massachusetts and Wisconsin. From June 30, 1976 through September 1981 three States--Hawaii, Massachusetts and Wisconsin--were eligible for hold-harmless. Starting in FY 1982, only Hawaii and Wisconsin were eligible for hold-harmless. The amounts received by each State from the beginning of the program in FY 1974 through FY 1982 are as follows:

California	$102,749,800
Nevada	1,039,434
New York	100,716,714
Hawaii	3,700,841
Massachusetts	118,458,942
Wisconsin	251,483,560
Total	$578,149,291

VERIFICATION OF INCOME AND ASSETS IN SSI AND AFDC

Question: What are you doing to improve the verification of the income and assets of recipients in the Supplemental Security Income (SSI) and Aid to Families with Dependent Children programs?

Answer: In the SSI program, we have established many computer match operations with Federal or State systems of records on an experimental or ongoing basis. The ongoing interfaces with Federal records include: (1) Veteran's Administration (approximately five times per year); (2) Railroad Retirement Board (once a year); (3) Office of Personnel Management (two times per year); (4) Department of Defense military pay records (once a year); (5) Immigration and Naturalization Service (manual process to detect payments made to deported aliens); and (6) Internal Revenue Service files (not yet operational). State matching operations include the following: (1) unemployment insurance benefit matches (two matches in New York State); (2) wage matches (ongoing in Massachusetts, Maine, Vermont, and Rhode Island)--Proposed for California, New York, and several other States; and (3) matches with bank records (ongoing in Massachusetts, planned in California). We intend to expand interfaces with the other Federal systems of record (daily interfaces where possible) and encourage additional State matching operations. State matching operations are not uniform nationally due to varying levels of sophistication of State systems of records.

For the AFDC program, SSA has an agreement with IRS that allows us to provide tax information to States who administer the

AFDC and Food Stamps programs. SSA has worked with State agencies to encourage use of the title II (OASDI) Benefit Data Exchange (BENDEX), the SSI State Data Exchange (SDX) and State computer data bases to verify client reported benefits and detect unreported amounts. States requesting automated systems development and operational funding under Section 406 of P.L. 96-265 will be required to interface with and use data provided by the BENDEX system.

RECOVERY EFFORTS IN AFDC AND SSI PROGRAMS

Question: Considering the magnitude of erroneous payments in the AFDC and SSI programs, to what extent have you established appropriate mechanisms for monitoring and evaluating the adequacy and effectiveness of recovery efforts in these programs?

Answer: SSA formulated a comprehensive plan in the latter part of FY 1981 to strengthen recovery policies, procedures, systems and management controls. Subsequently we completed a special analysis of outstanding debt and have been releasing delinquent debt to our field offices for prompt resolution. These and other debts owed by former beneficiaries will be controlled and monitored by an interim billing and follow-up system being installed in our processing centers. This system will routinely bill beneficiaries who are overpaid and trigger follow-up contacts when payment is not received. For the longer term we are working to establish a National Debt Management System. A contractor is currently interviewing all potential users of the system to ensure that their needs are included in performance specifications. When implemented the system will, among other things, enable SSA to monitor and evaluate the adequacy and effectiveness of recovery efforts in the SSI and other benefit programs directly administered by SSA.

In the AFDC program, the Omnibus Budget Reconciliation Act of 1981 mandated that States recover 100 percent of all overpayments. SSA has developed a recovery reporting form and secured OMB approval to collect AFDC information from States which will be used to assess the effectiveness of their recovery efforts.

APPLICATION OF CHILD SUPPORT ENFORCEMENT PROGRAM TO SSI

Question: Since the organizational structure for child support enforcement is already in place to locate absent parents and collect support payments in the AFDC program, what specific efforts have been made to expand the support enforcement policy so that it also applies to the Supplemental Security Income (SSI) program?

Answer: The Department of Health and Human Services has been examining the possibility of expanding the child support program to apply its provisions to certain blind and disabled children receiving supplemental security income. Several meetings have already occurred between the principal agencies, the Office of Child Support Enforcement, and the Social Security Administration, to discuss policy and operational issues and cost estimates.

Question: How much money do you estimate could potentially be recovered from absent parents of children receiving SSI payments?

Answer: This information is still being developed. In particular, the collections potential needs to be assessed together with the administrative cost and complexity of the effort.

RECONSIDERATION PROCESS AND HEARINGS BACKLOGS

Question: The current appeals process for people whose claims are denied or whose benefits are terminated by the Social Security Administration is made up to two major stages. The first, called a reconsideration, simply asks for a review of those who made the initial decision (not the same people but the same offices). If unsatisfied with the results of that review, a claimant may pursue the issue to the second stage, which is a formal hearing before an ALJ. Current data show that only 12 percent of the reconsiderations filed with the Social Security Administration result in favorable findings. At the same time virtually all who are denied at that level request a hearing. In 52 percent of those cases the negative reconsideration decision is reversed. The fact that the reconsideration process is largely ineffective is made worse by continued growth in the hearings backlog, now over 6 months worth on hand.

How does the Social Security Administration plan to tackle the related problems of a largely ineffective reconsideration process and a badly backlogged caseload for Administrative Law Judges?

Answer: As noted in response to a previous question, we are aware of the need for improving the reconsideration process and have already taken steps to prepare for the introduction of a face-to-face reconsideration hearing procedure in disability termination cases beginning on October 1, 1983, as required by P.L. 97-455. This procedure will make the reconsideration level more meaningful and in addition to improving the quality of decisionmaking at that level, will also contribute to speedier and more accurate decisionmaking at the subsequent levels of the appeals process. The Administration has also supported legislation to close the administrative record after the reconsideration level, thereby encouraging claimants to submit all evidence at that level.

At the same time we are continuing initiatives to reduce the number of pending ALJ hearing requests through:

--increases in the support staff-to-ALJ ratio to a level of 5:1. ALJ's can increase their rate of production with more support staff because the support staff can assist with pre-hearing case development and post hearing actions and the ALJ's can concentrate more fully on hearing cases,

--reconfiguration of hearing office staff to promote greater efficiency,

--improved hearing office word processing and dictating equipment, and

--more training for ALJ's and support staff.

SEPARATION OF PROGRAM INTEGRITY STAFF

Question: How do you see the new program integrity organizational structure more effectively dealing with the problems of fraud, waste and abuse?

Answer: The basic logic behind the move was to concentrate investigative resources where they could most effectively be used. To the extent that the SSA investigators are now working for and receiving direction from an organization whose primary purpose is to conduct criminal investigations, they should be in a position to carry out their functions more effectively.

Question: Will the separation of the Program Integrity staff from the Social Security Administration hinder efforts aimed at fraud prevention?

Answer: While there are potential problems in the separation, to date the two agencies have cooperated fully, and information is flowing from OIG to SSA about the cases under investigation. The information is tightly controlled in SSA, and provided only to those people who need to know. Additionally, information gathered during investigations will be made available for analysis by both SSA staff concerned with operational security and OIG staff. The intent is to use information discovered in the investigative process to develop better preventive and detection techniques. We also expect that results of special studies conducted by OIG will be readily available to SSA.

We are aware of no problems to date.

PREEFFECTUATION REVIEW

Question: What progress has been made to meet the congressional mandate that 65 percent of initial disability decisions be reviewed?

Answer: As required by P.L. 96-265, the Secretary reported to the Congress before January 1982 on the potential effects of the requirement for the 65 percent review. The Secretary's report contained a recommendation that the increase to 65 percent be deferred, supported by reasons for the recommended deferral. That recommendation was followed by legislative proposals to that end.

However, since it is now unlikely that legislative relief from the 65 percent review will be provided in the immediate future, SSA will be increasing the level of review so that the mandated 65 percent level will be reached by the end of the fiscal year. This Administration continues to support proposals to provide relief from the 65 percent review level.

DISABILITY ERROR RATES

Question: What steps does the Social Security Administration plan to take to improve the disability payment error rates?

Answer: In FY 1981 the Social Security Administration (SSA) implemented two operational reviews mandated by the 1980 disability amendments: periodic reviews and preeffectuation reviews.

Periodic Reviews

This review of nonpermanently disabled beneficiaries began in May 1981. Cases were selected for review according to the likelihood of cessation based on findings from a quality review study conducted in 1979 and 1980. During the period from May 1981 through March 1982, State agencies conducted about 190,000 continuing disability investigations (CDI's) as part of this provision. Benefit payments were terminated in 86,000 cases where the beneficiaries were found not disabled.

Preeffectuation Review

In fiscal year 1981 SSA reviewed, on a preeffectuation basis, 15 percent of all favorable State agency disability decisions (both new claims and continuances). The percentage of favorable decisions reviewed increased to 35 percent staffing in October 1981 and will be increased in fiscal year 1983. As a result of these preeffectuation reviews, some 2,400 erroneous favorable decisions in fiscal year 1981 and about 7,300 in fiscal year 1982 were changed to unfavorable and benefits were either not started in the case of new claims or they were terminated in the case of CDI's. Even after all appeals were exhausted, the preeffectuation reviews have the effect of reducing both incorrect cases and payments.

Quality Reviews

In addition, SSA carefully monitors State agency performance by conducting reviews of the quality (accuracy) of disability determinations. These reviews indicate a relatively high net accuracy rate--over 96.5 percent--on disability decisions. Where an individual State agency falls below acceptable levels of performance, SSA provides technical and management assistance to help the agency meet the performance requirements. Currently, SSA is providing assistance to 10 State agencies.

Question: Should quality assurance resources be shifted from the Old Age and Survivors Insurance program to other programs where rates are much higher?

Answer: We believe that it is necessary to look at how we use our quality assurance resources, and to shift those resources among the programs administered by SSA as experience warrants. In fact, since October 1980, due to a number of factors we have reduced the amount of staff resources spent on OASI, and some of those resources have been used for quality reviews in other programs.

However, the OASI program pays about $155 billion a year in benefit payments, and even the current .4 payment error rate produces erroneous payments of about $500 million. Therefore, we must keep a certain minimum level of review in the OASI program.

Also, it should be noted that the resources committed to OASI quality measurement activities do more than measure payment errors. Many other aspects of program management such as beneficiary compliance with reporting responsibilities, SSA adherence to current laws and operating procedures, and service to the public by way of notice accuracy and processing time data are also recorded so that constant attention is focused on any problems in these areas. A significant lessening of the resource commitment to these activities could be expected to adversely affect quality. This need for program management information will continue to be important as we implement the Social Security Amendments of 1983.

DISABILITY DENIAL RATES

Question: Why are disability denial rates so high?

Answer: The disability denial rates reflect the proportion of the applicant population that do not meet the requirements of the law. Numerous factors contribute to why so many such individuals file disability claims. These are, for example, the number of persons with minimal impairments who are required to file because they have sought other benefits, the state of the economy, and the unemployment rate. To make sure that claims are being properly decided, a regional Federal review is conducted of the State agency disability decisions and a centralized Federal review is made of the regional reviews to assure uniformity and accuracy. These reviews have shown that the vast majority of claims that are denied are done so in accordance with the provisions of the law and regulations.

STAFFING ALLOCATIONS BETWEEN DISTRICT OFFICES AND PROGRAM CENTERS

Question: What steps are planned to achieve a better balance in staffing allocations between district offices, which recently have failed to achieve expected workloads, and program service centers, which are getting badly backlogged?

Answer: Our budget plan for FY 1983 and FY 1984 includes a decrease in work-years from the 1982 level for the district offices, and an increase in work-years for program service centers (PSC's). Work-years may be achieved by full-time permanent employees, by part-time and temporary employees, or on overtime. Changes in work-year requirements are accomplished through periodic reallocations of staffing ceilings and overtime hours, taking into consideration such factors as employment turnover rates and the types of employees needed to do the work on hand.

The most expeditious way to reallocate work-year resources between components quickly is by adjusting overtime levels. We have done that with respect to the district offices and the PSC's. Overtime allocations to the field have been cut back, and

additional hours have been allocated to the PSC's. Many of the current heavy workloads in the PSC's are one-time or cyclical in nature, and, therefore, it is more appropriate to meet these needs through increased overtime rather than through reallocations of permanent staff. We also are looking at how implementation of the Social Security Amendments of 1983 will affect our overall staffing needs in the field and in the PSC's.

For the short-term, to deal with the current heavy workloads in the PSC's, primarily due to processing of recomputations of benefits--known as AERO--for beneficiaries with earnings in 1979 and 1980, we also have recruited district office employees on a volunteer basis to work overtime in the six PSC's. This program is working very successfully and, as a result, we plan to complete 1979 and 1980 AERO work by the end of June.

Question: In addition, what is the Social Security Administration doing to improve automated processing of the backlogged program center workloads?

Answer: The Systems Modernization Plan includes various improvements which will enable increased automated processing of workloads throughout the Agency. Two examples of budgeted projects that will affect workload processing in the program service centers are:

--Replacement of card readers used for case control and folder location in SSA's program service centers and Office of Disability Operations with scanning devices. The new system will be more reliable and efficient, and it will save clerical time in controlling folder movement. The budget includes $7.6 Million in FY 1983 and $.5 million in FY 1984 to fund this project. The cost of the project is partially offset by budgeted savings of 135 work-years and $3 million in FY 1984.

--Replacement of the obsolete computers in the program service centers and the Office of Disability Operations with up-to-date modern equipment with increased capacity for present and future applications. New equipment will reduce failure rates, decrease maintenance costs and increase productivity. The budget contains $7 million in FY 1984 for this project.

PROGRESS IN UPDATING EARNINGS RECORDS

Question: The Social Security Act requires periodic review of the earnings record of beneficiaries who continue to work. What is at stake, essentially, is an increase in benefit amounts following recomputations which reflect new earnings.

What progress has been made in bringing Social Security's earnings records up to date, so that benefit amounts can be more promptly recomputed?

Answer: Despite some remaining problems, SSA has made substantial progress since tax year 1978--the first year of the change from quarterly to annual wage reporting--in reducing the amount of time it takes to credit earnings to individual earnings records and to recompute benefits based on the new earnings.

AERO--Automatic Earnings Reappraisal Operation--is the term for the process by which, after calendar year earnings are posted, earnings records of beneficiaries are screened for possible recomputations and, where appropriate, increased benefits are paid.

Since 1978, delays in posting earnings under annual wage reporting resulted in delays in AERO. For 1978 earnings, it took SSA nearly 39 months to substantially complete the earnings posting process; for 1979 earnings it took about 27 months to do so. For 1980 and 1981 earnings it took about 15 months each. For 1982 earnings, we expect to complete the postings by December 1983, or within 12 months.

Many of the delays experienced early in the annual wage reporting process were due to the complex problems of making the change to annual wage reporting, such as completely redesigning SSA's wage reporting systems and educating employers about how to report accurately under the new system. We also had problems related to obtaining adequate computer time from SSA's obsolete systems, the first priority of which is to pay regular monthly benefits on time. Although we have substantially improved our annual wage reporting timing and procedures, the Systems Modernization Plan includes a redesign of the earnings system, which already has begun, as part of a longer-term improvement for the process.

As I mentioned, a timely AERO process to recompute benefit amounts depends upon timely posting of earnings after the close of the year. Ideally, we would expect earnings to be posted to individual records in the year following the year in which they were earned (e.g., 1982 earnings posted in 1983), and recomputed under AERO in the year following the year in which they are posted (e.g., benefits recomputed in 1984 based on 1982 earnings).

AERO for 1978 earnings was started in November 1980, and was 85 percent complete by the spring of 1981. A combined AERO process for 1979 and 1980 earnings, and remaining cases involving 1978 earnings, is currently underway. The number of manual actions required for 1979-1980 AERO cases has been greater than expected. Nevertheless, we plan to complete them by July 1, 1983, so that most benefit checks received by August 1983 should be up-to-date through 1980 earnings. Later this fiscal year we will begin AERO for 1981 earnings.

CHARGING FOR ADMINISTERING SSI STATE SUPPLEMENTATION

Question: In view of the significant costs involved to administer the optional supplemental security income supplementation on behalf of 27 States, what consideration has the Social Security Administration (SSA) given to the feasibility of charging States an administrative service charge?

Answer: Charging the States for administration of optional supplements would be contrary to the intent, and probably the letter, of the laws underlaying the SSI program. This is evident

from the legislative history as indicated in the Report of the Committee for Ways and Means on H.R. 1, May 26, 1971 as follows:

"Although, as noted above, your committee recognizes that there may be a continuing need for State supplementation of the new Federal assistance programs, it would appear generally desirable that such supplementation be provided through the same agencies which would be established to operate the Federal programs. This would avoid unnecessary duplication of administrative costs, would permit the States to take advantage of the improved methods and procedures which the bill would require, and would tend to foster national uniformity in the operation of assistance programs. Your committee's bill accordingly not only permits the States to enter into agreements with the Secretaries of Labor and Health, Education and Welfare which provide for Federal administration of State supplemental payments, but encourages such agreements by not requiring the States to make any contribution toward the administrative costs arising out of these agreements and by guaranteeing the States that agree to Federal administration against increases in the cost of making supplemental payments."

There was nothing in the subsequent (1977) report of the staff of the Committee on Finance of the U.S. Senate to contradict this.

To begin charging States for SSA's administrative costs would probably require amendment of section 1616 of the Act, which now provides only for payment by States of funds actually paid out to recipients by SSA on the States' behalf.

INCORPORATION OF GAO RECOMMENDATIONS IN SYSTEMS MODERNIZATION

Question: GAO has made recommendations in past reports for improving Social Security's Automatic Data Processing Operations, especially the controls in its software. To what extent have their recommendations been taken into account under the modernization effort?

Answer: The SSA Modernization Plan was developed after a thorough review of long standing systems weaknesses which had been repeatedly pointed out in prior GAO as well as HHS, GSA and OMB reports.

The agency has moved aggressively during the first year of the SMP to establish initial control on software activity. These actions include: a freeze on title II and program service center software systems changes, as well as, the establishment of a configuration change control board charged with assuring compliance with this principle and ending patchwork development; published a framework for a Software Engineering Technology (SET), through a cooperative effort with the General Services Administration, which addresses life cycle software development standards and methodologies; and, implemented software version release control to ensure adequate validation testing prior to release of software changes for production processing.

SYSTEMS RECRUITMENT AND SALARIES

Question: Has the agency made any progress in its recruiting efforts?

Answer: Since March 1981, when be began our recruiting effort, we have accomplished approximately 84 percent of our total projected hiring goal. The goal is the result of employment ceiling increases in conjunction with the implementation of the Systems Modernization Plan. Actual hiring has been accomplished in concert with organizational entities and positions. To date, 319 technical positions and 234 support positions have been filled from sources outside the agency.

Question: What can be done to make systems salaries the agency can offer more competitive with those in private industry?

Answer: Most systems personnel in SSA work in the GS-334 Computer Specialist job series. This job series covers a wide range of computer related work, including programming, systems analysis and equipment analysis. The problem of offering competitive salaries does not apply to the entire job series; although entry-level salaries generally are lower than those offered in the private sector, salaries at the journeyman GS-12 level generally are competitive. The principal area of difficulty is in hiring people to fill "high/super technical" positions. In situations where private sector pay rates are substantially above the statutory pay scale and Federal recruitment is significantly hampered as a result, an agency may request that OPM establish special rates of pay for a particular job series and grade. However, SSA would have a hard time making a case for the entire GS-334 Computer Specialist job series. One possible solution would be to obtain authority, similar to that which the Public Health Service Act once provided, to obtain the service of specially qualified professional, scientific and executive employees. Under this authority the Secretary of HHS was authorized to establish and fix the compensation for not more than 179 positions. The compensation level was to be no lower than the minimum GS-16 rate and no higher than the maximum GS-18 rate, or in the case of two positions, no higher than level II of the Executive Schedule. We understand that since the creation of the Senior Executive Service, the Office of Personnel Management was given authority (5 U.S.C. 3104) to set special compensation levels for specially qualified scientific and professional personnel--up to 517 positions government-wide. Unfortunately, the super high tech positions we need do not fall under this provision.

USE OF EMERGENCY ASSISTANCE FUNDS

Question: Your budget request includes $52,250,000 for the Emergency Assistance program, authorized under title IV-A of the Social Security Act. What do the States use these funds for?

Answer: Our budget request includes $52,500,000 for the Emergency Assistance program, authorized under title IV-A of the Social Security Act. The program authorizes Federal financial participation for an amount equal to 50 percent of the expenditures made by States for emergency assistance to families

with needy children. The emergency needs to be met, as defined by the States, include food, clothing, medical care and shelter.

Question: To what extent are the funds being used for non-emergency purposes or unallowable expenditures by the States?

Answer: We have discovered certain instances where States have made expenditures under the Emergency Assistance program which do not meet Federal guidelines. In each case, we are reviewing the circumstances and the State's position before taking disallowance action.

Also, on November 5, 1982 we informed States of our policies in several specific areas for defining eligibility and making payments to emergency assistance recipients. We believe that States are now in a better position to know what constitutes the permissible boundries for developing their Emergency Assistance programs.

SSI REDETERMINATIONS PROCESS

Question: What are the results of cost-effective analysis to see if this examination of the supplemental security income (SSI) rolls was worth the cost?

Answer: We reported to the General Accounting Office (GAO) in December 28, 1982, by letter, the results of an analysis of the cost-effectiveness of the redetermination process. In order to estimate the cost-effectiveness of the 1981 redetermination effort, we used findings from the Office of Assessment (OA) sample reviews of SSI cases to calculate the average monthly excess dollar error (i.e., amount overpaid) prior to and then after the redetermination. This calculation was performed individually for each separate redetermination category. Using this approach, we estimate that about $212 million in overpayments was prevented due to identification and correction of errors during redeterminations. This figure compares favorably with the $163 million cost for conducting redeterminations in 1981. In addition, the redetermination process serves as a deterrent to fraud; we are unable to fully quantify the costs that would occur if the redetermination process was not in place.

Question: What specific action has the Social Security Administration (SSA) taken, including the implementation of GAO and OA recommendations to reduce payment errors in the eligibility redetermination process?

Answer: We developed new forms to better structure redetermination interviews to obtain more accurate information. In addition, we have improved our abilities to target cases with potential for high overpayments and conduct intensive redeterminations. We targeted cases prone to income error for in-depth redetermination development. Improvements have been made to procedures (e.g., support and maintenance instructions) to make our rules easier to administer with less likelihood of administrative errors. SSA also established interfaces with OASDI computer records and with Veteran's Administration (VA), Railroad Retirement Board (RRB), and the Office of Personnel Management

(OPM) records (all federally-administered programs). Additionally, we have negotiated with States to conduct computer matches with unemployment, worker's compensation, disability, and bank records.

Question: What effect did such action have on reducing payment errors?

Answer: We believe that the actions SSA has taken have had a definite positive effect in reducing payment errors. Although it is not possible to precisely associate each specific action with consequent amounts of payment reduction, we can provide some data on our overall progress in reducing payment errors.

The payment error rate has dropped from 11.5 percent for the first half of 1975 to a low of 4.6 percent in 1978. Since that time, the rate has stabilized at about 5 percent. In dollar terms, excess payments were estimated to total $635 million in 1975, but were reduced to about $400 million in FY 1981. These reductions took place while overall program expenditures were increasing. In 1975, program costs for federally-administered SSI benefits were about $5.7 billion; in 1981, they totaled about $9.0 billion. If the error rate had not decreased, and had remained at 11.5 percent, excess payments would have reached $1,035 million for FY 1981. The difference of $635 million represents the amount that would have been erroneously spent if strong corrective actions had not been implemented.

We can provide savings estimates as to the effect of implementation of matching activities with records from other Federal agencies (Veteran's Administration, Railroad Retirement Board, Office of Personnel Management) and with our own earnings records from employers' reports. In the 6-month periods immediately before implementation of these data matches, about $65 million in excess payments was attributed to these income sources. This figure dropped to about $45 million for the 6-month periods after implementation. We, therefore, attribute the savings of $40 million/year to these specific corrective actions.

Question: What are the results of SSA's study in determining if the redetermination process was cost-effective?

Answer: In order to estimate the cost-effectiveness of the 1981 redetermination effort, we used findings from our routine payment accuracy reviews of SSI cases to calculate the average monthly excess dollar error (i.e., amount overpaid) prior to and then after the redetermination. Using this approach, we estimate that about $17.6 million in individual case overpayments were identified and corrected during routinely performed redeterminations. This figure translates to a $212 million savings in annual program costs due to prevention of misspent funds, which compares favorably to the $163 million cost figure cited. (These estimates were obtained from samples of cases and are, therefore, subject to some sampling variability.)

This $212 million figure only reflects savings from cases which continue in payment status after redetermination. There is an additional savings associated with case terminations, but

because these cases (i.e., cases no longer receiving payment) are not sampled in our routine review, we are unable to use this estimating technique to project a savings figure for these cases. A separate special study is in progress to develop savings data on this segment of the redetermination workload.

REFUGEE SOCIAL SERVICES

Question: Have the evaluations of refugee social services been completed, and what were their findings?

Answer: The evaluation study of refugee social services has not yet been completed; the final report is expected at the end of May. The preliminary findings show: a statistically significant relationship between vocational training and self-sufficiency; statistically significant evidence that employment services help refugees to get jobs; and consistent evidence that English language training contributes to the acquisition of English. A series of other studies since 1975 have consistently shown a close relationship between knowledge of English, labor force participation, and employment.

Question: What is the Office of Refugee Resettlement's (ORR) basis for determining the amount of social services funds overall that are needed to help refugees become self-sufficent?

Answer: For purposes of budget formulation, ORR's budget request for social services is determined on the basis of the 18-month adult population arrivals and average unit cost rates provided by the States.

Question: How does ORR know how much is enough?

Answer: Based upon past program experience, there is no reliable data which clearly establishes an easily quantifiable correlation between social services and accelerated refugee self-sufficiency. This is explained in part by local economic conditions, individual refugee socio-economic backgrounds as well as high geographic refugee concentrations. Under these circumstances, ORR's primary focus has been to assure that State social services expenditures are justifiable and directed towards those activities such as English language training and vocational training which are an obvious essential component of a refugee's effort to achieve self-sufficiency.

WELFARE DEPENDENCY OF REFUGEES

Question: What is the current estimated welfare dependency for recent refugee arrivals, and what steps are being taken to reduce this dependency rate?

Answer: Based upon data available to ORR, the welfare dependency for eligible refugee (i.e., those in the country less than 36 months), is estimated at approximately 52 percent. This percentage for the entire 36 month stautory period may be misleading in that the dependency rate on a State-by-State basis for recent arrivals is expectantly higher than the rate of those in this country 24 months or longer. In order to reduce the high

incidence of dependency for recent arrivals, every effort is being made by ORR to target State social services funding to this recent arrival group to help them achieve economic self-sufficiency before exhausting their cash and medical assistance benefits.

Question: What has been the effect of the provisions of the Refugee Assistance Amendments that would further limit refugee eligibility for cash assistance?

Answer: Since the Amendments were enacted October 25, 1982, and States required time for implementation of the changes, data are not currently available to permit an analysis of effects. We consider the new provisions--which provide for immediate employment registration, mandatory referral to job or language training, early termination of assistance for refusal to accept employment or services, required contacts between welfare and resettlement agencies, and the prohibition of refugee assistance to full-time college students--to be important advances in achieving more effective resettlement of refugees.

Question: Do you now support the proposal that refugee medical assistance eligibility be separated from cash assistance eligibility?

Answer: We understand the term "separation of medical assistance from cash assistance" to refer to the setting of higher financial eligibility limits for medical than for cash assistance so that medical assistance may be continued if a refugee's income is above the cash assistance eligibility limit but within the higher limit prescribed for medical assistance. A variation of this definition would be that medical assistance would be available to refugees for a specified period--e.g., 12 or 18 months--after their arrival in the United States without regard to income. Under current policy, those refugees who are eligible for Medicaid are included under that program and other refugees who meet the Medicaid financial eligibility requirements, but do not meet other Medicaid requirements (such as family composition), are aided under the special program of refugee medical assistance during their first 18 months in the U.S. In determining eligibility for the refugee medical assistance program, the same financial eligibility limits are applied as in the State's Medicaid program. If a given State has a Medicaid medically needy program under which medical assistance (but not cash assistance) is provided to persons whose income is above the cash assistance level but within specified limits, then the refugee medical assistance program in that State also has a medically needy portion, under which medical assistance (but not cash assistance) is provided. The Department believes that the greatest possible equity in the provision of medical assistance between refugees and American citizens is an overriding consideration and therefore does not support proposals which would provide further refugee eligibility for medical assistance beyond the eligibility of citizens.

Question: What were the findings of the analysis of this subject that was mandated by the Refugee Assistance Amendments?

Answer: We concluded that while there is considerable concern about the provision of medical assistance to refugees, and its general linkage with cash assistance, we do not see any single, feasible, and currently advisable alternative to the present system. The linkage of medical to cash assistance is a basic element of overall U.S. welfare policy and to change it solely for refugees would increase the differences in treatment between refugees and other needy Americans at a time when we are attempting to ensure greater equity; could create significant administrative problems; with attendant costs; and would abrogate our basic policy of following existing State systems and practices in the provision of assistance.

Question: What has been the impact of the 18-month cash and medical assistance policy in terms of reduced costs and caseload?

Answer: Prior to the policy change about 67 percent of all eligible refugees were receiving some form of cash assistance. Based upon a nine-State survey conducted by ORR during the summer of 1982, approximately 52 percent of all eligible refugees were found to be receiving cash assistance. During FY 1982, after 5 months of complying with the policy change, there was an estimated savings of between $60-$70 million. Program savings are estimated at between $80-$90 million in FY 1983.

ORR does not have more specific data on the consequences of the policy changes at this time. However, the results of an extensive study ORR has funded on the self-sufficiency of Southeast Asian refugees will provide more information. These results are expected to be available in May of 1983. Some data, however, collected by State agencies, voluntary agencies and others does indicate a range of results, i.e., many refugees went to work, some moved to States with AFDC UP programs or GA programs while still others moved to places where jobs were available.

Question: Is there any evidence that the 18-month policy resulted in refugees' migration to States with general assistance programs?

Answer: Yes, secondary migration to States with AFDC-UP and/or general assistance programs was one of several responses which refugees chose from among their possible options. However, it is ORR's experience that, while the potential for receiving public assistance may attract time-expired refugees to certain areas, the availability of assistance is not an exclusive determinant of why or where refugees relocate. Among other important considerations are: (1) availability of jobs, (2) climate, (3) available ethnic support systems, and (4) availability of services.

Question: Have any States refused to continue their participation in the refugee assistance program as a result of the 18-month policy?

Answer: No, none has refused.

Question: Did the "targeted assistance" program prove to be a reasonable response to those States particularly hard hit by the policy change?

Answer: Yes, we found a very positive response to the availability of targeted assistance funds for Cuban and Haitian entrants in FY 1982 and also the availability of targeted assistance funds for both refugees and entrants in FY 1983.

Questions Submitted by Senator Proxmire

Question: You propose to maintain your staffing level at 90 positions next year despite the fact that refugee admissions are expected to average 1,000 per month less than in fiscal year 1983 and despite a simplified grant program that would eliminate targeted assistance and education assistance for children. Why can't you achieve some staff economies given these changed conditions?

Answer: Reduced refugee flows under the State-administered programs for refugee and entrant domestic assistance will not affect the nature or scope of ORR's statutory responsibilities for program development and direction, program and fiscal monitoring, data collection or national initiatives for more effective and efficient refugee and entrant resettlement. In addition, ORR will continue its efforts to develop favorable sites and the implementation of a national refugee placement policy. In FY 1984 ORR will undertake special efforts in Hmong resettlement and will conduct quarterly consultation meetings with State Refugee Coordinators and other State, local and private officials to review and plan national resettlement efforts and special problem areas.

It is not realistic to interpret ORR's FY 1984 budget as merely introducing a simplified grant program that eliminates targeted assistance and educational assistance for children. The FY 1984 budget does however introduce a different direction and methodology for refugee and entrant domestic assistance at the State and local levels. The new State per capita grant programs will introduce an added program of widely varying refugee and entrant assistance modes which will significantly impact on the national resettlement of refugees.

The changes being introduced under ORR's FY 1984 budget do not reflect a reduction in the Federal role or responsibility for refugee and entrant resettlement. Therefore, at this point in program development and implementation a reduction in Federal staff resources is not considered prudent or warranted in FY 1984.

Question: A recent General Accounting Office study found (1) a lack of a clear strategy for resettling refugees, (2) insufficient emphasis on early employment for refugees, and (3) limited program monitoring at the Federal and State levels.

Under a per capita program how would your office make sure that States give priority attention to job development and

placement activities for refugees and follow other refugee program policies, goals and objectives developed at the national level?

Answer: The Administration is proposing the per capita grant in order to provide maximum flexibility to the States to determine their priority needs in offsetting refugee impact and promoting early self-sufficiency. We believe that States are better equipped to identify and respond to the needs of refugees in the State than the Federal Government. A State will be able to make its own decisions about the allocation of the per capita grant funds within the broad range of assistance and services allowable under the Refugee Act.

Question: Under a per capita grant program there could be a substantial amount of diversity among the States in providing refugee assistance. Couldn't this result in refugees seeking those States which offer them the more tangible economic benefits?

Answer: There is currently substantial diversity among States in refugee assistance since there is great variation in AFDC and general assistance programs. This diversity is also currently reflected in the special program of refugee cash assistance since it is based on each State's AFDC financial eligibility standards and payment levels. It is correct that an additional degree of diversity could occur under the per capita grant since a State would no longer be required to have a special refugee cash assistance program available during a refugee's first 18 months in the U.S. If a State without a comprehensive general assistance (GA) program were to decide not to have a program of refugee cash assistance, this would certainly have an affect on refugees resettled in that State who were not able to become employed during the initial period of voluntary agency support and could result in their moving to a State with available economic benefits. In such a circumstance, we believe that the lack of availability of backup assistance would also be a factor affecting the planning of voluntary agencies with respect to whether to resettle refugees in a given State.

Question: The table on page 14 of your justifications indicates that no funds will be provided for targeted assistance. However on page 22 those justifications state: "The Administration's FY 1984 per capita request includes $35 million in targeted assistance." Does this mean that States will have to use at least this much of their per capita grant funds to assist refugee/entrant populations in areas where supplementation of available resources is necessary because of a high concentration of refugees and entrants?

Answer: ORR's budget justification indicates on page 14 that no Federal funds are being requested in FY 1984 as a separate budget line authorization. However, as indicated on page 22, Federal funding in the amount of $35 million is requested for targeted assistance as part of the Federal grants being provided to States on a per capita basis. States will have wide discretion and control in the allocation of its per capita grant resources to meet refugee and entrant needs according to local requirements and situations as it determines to be necessary. However, in general, it is expected that the ability to federally target funds to a few impacted areas will be lost under the per capita grant proposal.

COORDINATION OF REFUGEE PROGRAMS

Question: A task force report of the President's Private Sector Survey on Cost Control had this to say about the Office of Refugee Resettlement:

"Even though the Task Force assignment was limited to the refugee function in the Department of Health and Human Services, the Task Force did get a glimpse of the fractionated responsibilities existing among HHS, the State Department, the Justice Department, and the Refugee Coordinator (who had no authority or responsibility but a large budget)." The Task Force went on to suggest a separate study to consider consolidation and/or more effective coordination and use of these program funds that cross several departmental lines.

Do you agree with these comments?

Answer: These recommendations will be given very careful consideration. Increased coordination among Federal agencies with respect to refugee policies and programs has been a major objective of this Administration, and close, continuing relationships have been established among the concerned departments and agencies.

AUTHORIZATION OF REFUGEE PROGRAMS

Question: Director Hawkes, on page 11 of your justification you indicate that your budget request is already authorized. On page 15 you state that the statute expires at the end of FY 1983. Which statement is accurate?

Answer: ORR's budget justification indicates on page 11 the legislation which has authorized Federal funding for refugee and entrant assistance in FY 1983. The statement on page 15 of the justification is meant to indicate that the Refugee Act of 1980 will require congressional reauthorization for continued Federal funding in FY 1984.

Question: You plan to establish a $270,116,000 per capita grant program in the coming fiscal year. This seems a pretty dramatic departure from your current program. Will it require a change in your authorization?

Answer: A reauthorization bill is being prepared at this time and will be submitted to the authorizing committees as soon as possible.

Question: What sort of a formula would you use in distributing per capita grant funds to the States?

Answer: Distribution of the per capita grant funds would be based on each State's proportion of the national population of refugees who had arrived during th three fiscal years immediately preceding the fiscal year for which the funds were appropriated. Five percent of the funds would be held until no later than the end of the second quarter to allow for any necessary adjustments in the population estimates. Up to 2 percent of the funds would be reserved for research, demonstration, or similar projects to

test new ways of assisting or resettling refugees. The remaining 93 percent of the funds would be awarded to States at the beginning of the fiscal year or as soon as funds are apportioned to ORR.

LOW INCOME ENERGY FORMULA

Question: You state on page 177 of your justification that your budget request for low income energy assistance is based upon the enactment of new legislation which will change the allocation formula to target funds to those States with the greatest need. Spell out the specifics of the formula, if you would.

Answer: We will propose a formula which sends a greater proportion of the available funds to the States with the highest heating costs. The current distribution is based on a series of formulas which were computed last in 1980. Details regarding the formula changes will be provided, as soon as the bill is cleared by the Administration.

Question: If we appropriate funds on the basis of a formula that has not as yet been put together aren't we in essence simply giving you a blank check for the distribution of these funds?

Answer: The exact formula will be contained in the legislation submitted to the authorizing committees. The appropriation language included in our request was intended to alert the Committee of our intention to change the formula.

Question: How will your proposal further simplify administrative requirements placed on States as noted in your justification?

Answer: While we have not yet submitted a bill to Congress, I can mention where we expect to propose simplification:

- o further reducing the number of assurances to be included in the application;
- o making the application process more like the simpler one used by other HHS block grants;
- o further reducing and streamlining Federal reporting requirements;
- o requiring a biennial, rather than annual audit, and so bringing the audit requirement into line with other HHS block grants.

STATE ADMINISTRATIVE FUNDS IN ENERGY PROGRAM

Question: States may use up to 10 percent of their funds for administrative expenses. What percentage of the funds are used by the States for administrative expenses on the average and what are the highest and lowest percentages devoted to administration among the 50 States?

Answer: We won't know every State's administrative costs for FY 1982 until audits are received and reviewed. However, most States voluntarily reported some information to HHS and the

American Public Welfare Association beyond what the law requires. Of these, 33 States reported administrative costs of about 7 1/2 percent of expenditures in FY 1982. That is significantly less than the 10 percent allowed by law. Also, these 33 States represent a self-selected sample. They are not necessarily representative of all States.

ENERGY COSTS FOR LOW INCOME FAMILIES

Question: Do we have any idea of what percentage of their incomes families receiving low income energy assistance spend on residential energy costs?

Answer: Our August 31, 1982 report to the Congress on the FY 1981 energy assistance program included estimates of the energy costs borne by low income households for that year.

Households with incomes at or below 125 percent of the poverty income guidelines spent about 18 percent of their income on all residential energy (excluding gasoline and wood). This varies from 27.1 percent in the northeast to 10.8 percent in the West. For space heating alone, the range was from about 25 percent of income for fuel oil users in the Northeast and North Central regions to about 6 percent for natural gas users in the South and West.

We are currently analyzing data from the Department of Energy's Residential Energy Consumption Survey and the Bureau of Census 1982 Current Population Survey to derive comparable information on Low Income Home Energy Assistance Program (LIHEAP) recipients as distinguished from low income households in general. These fundings will be provided in the FY 1982 LIHEAP annual report to Congress later this year.

Question: Has the Administration ever attempted to determine how many Federal dollars it would take to pay all but a specified percentage of a low income family's energy costs -- how much it would cost, for example, to reduce the amount a family pays to 10 percent of its income?

Answer: We have performed extensive analysis of the energy costs borne by low income households. However, to know how many LIHEAP dollars it would take to reduce the energy burden of all low income households to 10 percent of their incomes, it is necessary to know how many Federal dollars already are being provided for energy costs through other programs providing for basic needs or housing subsidies. By its funding decisions over the last 3 years, Congress has indicated that LIHEAP is not intended to pay the entire energy costs of low income households, but is to supplement assistance provided through other programs.

We are developing estimates of the amount of energy assistance being provided by other programs. The results will be included in our report to Congress on the FY 1982 LIHEAP.

Question: The Low Income Energy Assistance Program has been in operation since fiscal year 1980, when it was started as an emergency program to help people cope with rapidly rising energy costs. Many fuel prices have stabilized over the past few months

yet the Administration plans to spend $1.3 billion on the program in 1984. Does this mean that the program should be considered a more or less permanent part of the regular welfare system?

Answer: As early as FY 1978, Congress began appropriating funds to help low income households experiencing energy crisis. While the authorizing legislation for the predecessor program stated that its purpose was to help low income households offset the rising costs of home energy, mention of the rise in costs is absent from title XXVI of P.L. 97-35, which authorizes the current Low Income Home Energy Program (LIHEAP).

While the price of home heating oil has declined somewhat over the past year, prices of natural gas and electricity have risen significantly. More than half of all low income households use natural gas to heat.

We believe that energy assistance programs will continue to meet a genuine need for some time. However, we believe States should have maximum flexibility to assess the need for energy assistance among their own citizens and to design mechanisms to provide such assistance. Accordingly, we have proposed that LIHEAP be one of the programs included in the State Fiscal Assistance Block Grant included in the President's federalism initiative.

AFDC FISCAL SANCTIONS

Question: As you know, the law requires you to impose fiscal sanctions on States that fail to meet AFDC target error rates. Your budget assumes that sanctions will be levied against the States in the amount of $75 million in fiscal year 1983 and $135 million in fiscal year 1984. However, page 99 of your justification narrative states the law allows for waivers of disallowances based on good faith efforts by the State and indicates you have not yet determined whether or not such waivers will be granted. When will this decision be made?

Answer: On March 10, 1983 SSA sent notices to 28 States which did not meet the target error rates. States have 65 days to request a waiver based on "good faith" efforts to improve their performance. We will promptly evaluate their waiver requests based upon criteria established in regulations.

Question: On page 104 of your justifications you say that you will not collect actual sanctions for the 1981 reporting periods until 1983 although you earlier assumed that you would be collecting 1982 sanctions this year. What has caused the delay?

Answer: Disallowances cannot be collected until all quality control data is obtained and appeal rights have been exhausted. We have recently issued regulations to expedite the review process. Presently, this process takes over a year. The specific reasons for the delay include: 1) having to conduct a subsample of cases after the review period ends which takes about 3 - 4 months; 2) permitting States to appeal differences between their data and the Federal Review; and 3) allowing SSA time to prepare the data for processing.

Question: Do you intend to charge interest on disallowances based on the 1981 reporting periods?

Answer: A regulation package to charge interest has been developed by SSA. However, the regulation's implementation has been delayed due to language in P.L. 97-365, "The Debt Collection Act of 1982" which appears to exempt certain SSA programs from charging interest.

Question: On page 98 of your justification you say "the State error rate for fiscal year 1982 has not been determined" although you estimate a rate of 6.1 percent. That was over 2 months ago. Can you tell us now what the actual rate was for 1982?

Answer: This information is not yet available. The data for FY 1982 is still being collected. The 6.1 percent represents our projection for FY 1982 based on the FY 1981 error rates. We believe that is a realistic projection.

SSI ERROR REDUCTION ACTIVITIES

Question: You project a savings of $148 million in the Supplemental Security Income (SSI) program next year as a result of error reduction initiatives. What are errors currently costing the Federal Government?

Answer: In the most recent 6-month reporting period of October 1981 to March 1982 for which actual data is available there was a total of $201,626,586 of overpayments in error from both Federal benefits and federally-administered State supplementation. Approximately 79 percent of the total payments for Federal benefits and federally-administered State supplementation is for Federal benefits. However, we do not know the precise percentage of the overpayments which are associated with Federal benefits alone.

Question: Your justifications indicate that SSI program costs are higher where a State elects Federal administration of its supplementation payments because the Federal Government bears the costs of administration and assumes fiscal liability for certain payment errors. What is the average payment error rate for State-administered SSI programs as compared with the rate associated with federally-administered programs?

Answer: We do not have a compelling reason to collect data on the payment error rate for State-administered supplementation and therefore we can not provide a comparison of payment error rates in the State-administered programs with the federally administered program. However, no matter how high the error rates are for State-administered supplementation, there is no expense to the SSI appropriation.

If a State opts for Federal administration of its supplementation there are two additional categories of cost to the Federal Government which are borne by the SSI appropriation. The first is the administrative costs associated with paying the supplementation. By law, these costs are borne by the Federal Government. The second is the Federal fiscal liability for any

erroneous payments of federally-administered supplementation in excess of tolerance error rates specified in contracts with these States. Neither of these categories of cost are incurred by SSA for the States that administer their own supplementation programs. Where a State administers its own supplementation payments, it bears the full administrative costs of making these payments and the full cost of any erroneous supplementation payments it makes.

Question: Do you have a long term error reduction plan? If so describe it now and provide details for the record.

Answer: We recently developed a comprehensive approach to planning modifications to the Supplemental Security Income (SSI) program which is under consideration by the Social Security Administration Executive Staff. Error reduction implies a reduction in program costs. Our proposed plan is more global. The aims are: (1) program simplification; (2) cost reduction; and (3) efficient program management. The document referred to herein is not yet final and therefore it would be premature to distribute it to this committee. However, it does have the following generic components: (1) legislative proposals for program simplification at reduced program costs; (2) expansion of Federal/State computer match activity to reduce payment errors; and (3) revision of existing quality assurance operations to produce data more useful for expeditious implementation of corrective actions. The document that results from this exercise on developing SSI goals will be a blueprint for efficient program management and cost reduction.

Question Submitted by Senator Lawton Chiles

Question: Last year this Committee expressed concern about the adequacy of the Systems Modernization Plan to accommodate changes Congress is making, and will be continuing to make, in Social Security formulas and benefits in the coming years. Report language required the Department to incorporate recommendations by the GAO in the Systems Modernization Plan. Are you on schedule with the plan and when will you have your next report to this Committee on the progress made on the report language?

Answer: Yes, we are on schedule with the Systems Modernization Plan. On March 1, 1983 Commissioner Svahn sent to Chairman Hatfield the first report on SSA's progress in modernizing and upgrading its computer systems. This report summarizes progress of management and technical initiatives, including:

--award of a Systems Engineering and Integration contract to provide continuous private sector management and technical engineering support to the Systems Modernization Plan,

--completion of a large-scale disk purchase to enable us to begin converting SSA's sequential tape files to direct access storage,

--acquisition of two modern large-scale processors to replace the overloaded central processors used for SSA's telecommunications

network which links the agency's field offices with the central computer facility,

--initiation of the design of a new annual wage reporting system, and

--improvements to SSA's Program Development and Test Facility.

The Senate report on the FY 1983 Health and Human Services appropriations bill directed the Department to report by June 30, 1983 on modifications to the Systems Modernization Plan:

--to provide for flexibility to accommodate legislative changes, and

--to include improved security measures.

We will report to the Committee on these issues by June 30, 1983.

SUBCOMMITTEE RECESS

Senator WEICKER. I thank you very much for your testimony.

The subcommittee will recess until tomorrow morning at 9 a.m. when we consider the request of the Health Care Financing Administration.

[Whereupon, at 9:35 a.m., Thursday, April 7, the subcommittee was recessed, to reconvene at 9 a.m., Friday, April 8.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1984

FRIDAY, APRIL 8, 1983

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, D.C.

The subcommittee met at 8:33 a.m., in room SD–116, Dirksen Senate Office Building, Hon. Lowell P. Weicker, Jr. (chairman) presiding.

Present: Senators Weicker and Proxmire.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HEALTH CARE FINANCING ADMINISTRATION

STATEMENT OF DR. CAROLYNE DAVIS, ADMINISTRATOR

ACCOMPANIED BY:
JAMES SCOTT, ASSOCIATE ADMINISTRATOR FOR OPERATIONS
DENNIS FISCHER, DIRECTOR, OFFICE OF MANAGEMENT AND BUDGET
ANTHONY ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET, DHHS

BUDGET REQUEST

Senator WEICKER. The hearing will come to order.

Today we shall hear the fiscal year 1984 budget requests for the Health Care Financing Administration, which has responsibility for administering the medicaid and medicare programs.

With a staff of more than 4,300, the Health Care Financing Administration has jurisdiction over a budget which, in fiscal year 1984, will total about $86 billion.

Of that total, some $46 billion covers benefits paid from the hospital insurance trust fund to medicare beneficiaries. And this portion of the agency's budget is outside the jurisdiction of this subcommittee.

The remainder of about $39 billion, is in appropriated and transferred funds that is within our subcommittee's jurisdiction. For fiscal year 1984, this will include about $21 billion for medicaid and $17 billion for payments to the health care trust fund, most of it for the Government's share of the doctor bill insurance available to beneficiaries.

The chief witness this morning is Dr. Carolyne Davis, Administrator of the agency.

Dr. Davis, we welcome you and your staff.

PREPARED STATEMENT

Why don't you introduce your staff? Your complete statement, in its entirety, will be included in the record.

Maybe you would care to go ahead and summarize it.

It's nice to have you here.

[The statement follows:]

STATEMENT OF DR. CAROLYNE DAVIS

I am pleased to appear before you to present the FY 1984 budget for the Health Care Financing Administration. To provide you with a better perspective of our appropriations request, I would like to briefly discuss the context in which it was prepared.

This budget addresses one of the most difficult issues facing the American people today: spiraling health care costs. The high cost of health care hurts each and every one of us--poor and affluent, young and elderly. It hurts us both as individual consumers and as taxpayers, since 40% of all hospital bills are paid through the Medicare and Medicaid programs. Clearly, the most vulnerable among us are the elderly and the poor. They are totally dependent on the ability of the nation to pay for the Medicare and Medicaid programs. Unfortunately, that ability is rapidly diminishing.

Over the last five years, Medicare benefit costs increased at an average annual rate of 19 percent. Total health care costs in 1982 rose at almost three times the national inflation rate. To give you a better idea of the direction in which we are heading, the Medicare and Medicaid programs will outlay as much each month in 1983 as they did during all of 1967, the first full year of their operation. It is a direction which is rapidly becoming unaffordable.

If not successfully checked, the increasing cost of health care threatens to bankrupt the Medicare Trust Funds as early as 1990 (under current actuarial assumptions) thereby endangering access to affordable care for some 30 million elderly and disabled Americans. Escalation of health care costs will also put enormous pressure on State and local governments to reduce benefits now provided through Medicaid to a needy population of over 22 million, and will increase the Federal deficits.

Over the last two years, this Administration and the Congress have joined together to counteract the ravaging effect of inflation on the Federally financed portion of the health care system. The Omnibus Budget Reconciliation Act of 1981 and the Tax Equity and Fiscal Responsibility Act of 1982 had significant impact on the inflationary spiral of Medicare and Medicaid costs. These laws are working, but they represent only a beginning to the reform effort.

Our fiscal year 1984 plan proposes to further address the underlying problems causing spiraling health costs: (1) the inflationary incentives inherent in the health care system, such as cost based hospital reimbursement, and (2) poorly structured cost sharing policies, which penalize the severely ill. In late February, the Administration submitted legislative proposals which seek to reverse those incentives, rather than trying to cap expenditures either through artificial cost limits or regulation. Among them is the proposal to limit the tax preference associated with costly private health plans provided by employers.

The centerpiece of this reform effort is the establishment of a Medicare prospective payment system for hospitals to create greater competition and efficiency in the health care marketplace.

As you know, Congress approved the prospective payment system as part of the Social Security Amendments of 1983. We can all applaud our efforts resulting in recent passage of this important change. Other major elements of Medicare reform provide catastrophic coverage for the first time, restructure cost sharing principles to encourage cost awareness while reducing financial burdens on the severely ill, and expand opportunities for beneficiaries to use their benefits to enroll in private health plans. Our Medicaid proposals include several initiatives designed to stimulate more cost conscious behavior by beneficiaries, to maintain incentives to reduce program growth at the State level, and to improve the efficiency of program operations. Coupled with the President's proposal to limit the tax subsidy on high cost private health plans, this budget calls on all segments of the health care system to work in unison to control costs. These innovative proposals share fairly - among providers, physicians, beneficiaries, employers, and privately insured workers - the responsibility for bringing down health care costs for everyone.

I would now like to discuss the highlights of our appropriations request.

The total fiscal year 1984 budget for the Health Care Financing Administration, including Medicare benefits, is $85.6 billion in outlays, an increase of $8.9 billion, or 12.0% over FY 1983. Our appropriation request of $38.2 billion, with $1.0 billion to be transferred from the Medicare Trust Funds, will finance the following activities in FY 1984:

- o $20.7 billion -- for Grants to States for Medicaid
- o $17.3 billion -- for Payments to Health Care Trust Funds
- o $30 million -- for Research and Demonstrations
- o $837 million -- for Medicare Contractors
- o $73 million -- for State Survey and Certification
- o $5 million -- for End-Stage Renal Disease Networks
- o $201 million -- for Administrative Costs

Grants to States for Medicaid

The request for Medicaid is $20.7 billion. Both the FY 1983 and 1984 budget estimates assume passage of the Administration's legislative proposals. Major legislation proposed for Medicaid includes:

- o Extension of reduction in Federal payments at a 3% level,
- o Mandatory cost sharing by Medicaid beneficiaries, and
- o Improvement of third party payor collections.

The 1981 Reconciliation Act and the 1982 Tax Act have significantly enchanced the States' ability to manage and control their Medicaid programs. One example of this has been evident in States' response to waivers for less costly home and community based services. As of March 31 a total of 66 separate waiver requests have been received from 40 States. To date, we have approved 38 requests in 31 States with 19 requests still pending consideration. These waivers will allow the States to provide services in a manner that they choose, with Federal oversight required only to ensure that the programs do not end up costing more than they would have cost without the waivers. Another example of this is in the States' response to freedom of choice

waivers. As of March 31, a total of 57 waivers have been received from 21 States. To date we have approved 29 with 8 pending. These waivers will allow States to better control inappropriate use of high cost health care departments.

Payments to Health Care Trust Funds

Our FY 1984 request for this account is $17.3 billion, an increase of $1.9 billion over the level authorized under the FY 1983 Continuing Resolution. The request is comprised of the following elements:

- Federal payment for Supplementary Medical Insurance -- $16.3 billion,
- Hospital Insurance for the Uninsured -- $750 million,
- Military Service Credit -- $207 million, and
- Hospital Insurance for Uninsured Federal Annuitants (costs created by the Tax Equity and Fiscal Responsibility Act of 1982) -- $42 million.

The Social Security Amendments of 1983 will impact on our request for this account. When we have finalized our estimates, we will get back to the Committee with our amended request.

Program Management

The request for program management is $1.1 billion -- $83 million in budget authority and $1.0 billion to be transferred from the Medicare trust funds. It supports the following activities:

1. **Research**

   We are requesting $30 million for research in FY 1984. Because this represents the same level of funding authorized for both fiscal years 1982 and 1983, our FY 1984 request represents a more sharply focused research and demonstration agenda committed to the selection of projects supporting priorities established in FY 1982 and 1983, including health care delivery competition, prospective payment, and program cost savings. Prior investments in research, demonstration and evaluation have been highly cost beneficial. We estimate that they have resulted in FY 1984 Medicare and Medicaid savings of at least $2 billion.

2. **Medicare Contractors**

   Our FY 1984 request for Medicare Contractors is $837 million, a net increase of $17 million, or 2%, over the FY 1983 Continuing Resolution. This amount includes the supplemental $45 million authorized by the Tax Equity and Fiscal Responsibility Act of 1982 for audits and medical reviews. It does not include a workload contingency fund. The majority of the total budget of $837 million is needed for essential claims processing functions. The remainder of the request provides for an adequate level of payment safeguard activities which result in Medicare program savings, and reflects a continuation of the effort to modify Contractor operations, wherever feasible, to induce greater efficiency and economy.

3. **State Survey and Certification**

We are requesting $73 million for State Certification in FY 1984: $38 million for Medicare survey activity and $35 million for Medicaid. The total represents a net program decrease of $1 million below the FY 1983 level. Increases for such items as the survey of newly eligible facilities (including 1,500 hospices) are offset by savings which result from the continuing implementation of a flexible survey cycle.

4. **ESRD Networks**

We are again proposing to eliminate the End-Stage Renal Disease Network Coordinating Councils because of their ineffectiveness. Pending termination of this activity through legislative action, funding of $5 million is requested for FY 1984.

5. **PSRO/PRO**

Our FY 1984 budget requested no funding for PSRO/PRO, reflecting our belief that the prospective payment system obviated the need for such a program. This budget was developed prior to Congressional passage of the Social Security Amendments of 1983, which require that hospitals have contracts with PROs in order to be eligible for Medicare reimbursement. Accordingly, we are reassessing our budget in this area, and will advise you of any changes which are necessary.

6. **Administrative Costs**

Our request for HCFA operating costs is $201 million, which represents a net funding increase of $7 million, or 4%, over the FY 1983 Continuing Resolution level. The request reflects a reduction of 256 authorized permanent positions through the elimination of duplicative and/or non-critical functions. This reduction underscores HCFA's commitment to the President's objective of staffing the agency at the minimum necessary for the effective and efficient operation of its programs.

That concludes my prepared remarks, Mr. Chairman. I will be happy to answer any questions the Committee may have.

INTRODUCTION OF ASSOCIATES

Dr. DAVIS. Thank you very much, Mr. Chairman.

To my left is Mr. Dennis Fischer, who is the head of our Office of Management and Budget.

And to my right is Mr. James Scott, who is my Associate Administrator for Operations.

And on his right is Mr. Tony Itteilag, who represents the Department's Budget Office.

Let me just summarize my statement briefly.

This statement differs slightly from the initial statement that we provided for the record because we needed to give you updated waiver information. I think we are submitting a corrected copy of that.

As you well know, the budget that we have proposed for this year addresses spiraling health care costs, which do tend to hurt everyone, especially the elderly and the poor.

I'm sure you're aware of that fact that 40 percent of all hospital bills are paid through our medicare and medicaid programs, and that medicare benefit costs have been increasing on an average of 19 percent annually in medicare over the last 5 years.

Indeed, in 1982, total health care costs rose almost three times more than the national inflation average.

I think it's interesting to note that the combination of medicare and medicaid outlays in 1 month for 1983 total as much as they did for the entire first year of the program, 1967.

We believe that unless these kinds of increases are checked that we're going to face a very serious threat to the fiscal solvency of the medicare hospital insurance trust fund. Our current projections are that under our actuary's assumptions, the so-called II B assumptions, the trust fund would be broke by 1990. That even takes into account the impact of the recently enacted Social Security Amendments of 1983. Using the most pessimistic fund assumptions the so-called III assumptions, the fund would be depleted by 1988. This would, of course, endanger access to care for our 30 million medicare beneficiaries and would increase the Federal deficit if we had to resort to a general revenue bail out of the system rather than restraining outlays now.

Obviously, Congress and the administration need to work together to solve this problem. We have already begun work in this area, largely through the initial efforts that occurred in the Omnibus Budget Reconciliation Act of 1981 and the Tax Equity and Fiscal Responsibility Act of 1982. But in 1983 and 1984, we need to continue with our reforms to address the problem of spiraling health costs.

We believe that cost-based hospital reimbursement was one of the most significant problems. And clearly, Congress has spoken to this, since they passed the prospective payment system as a part of the Social Security Amendments of 1983. This, we believe, will create greater efficiency and competition in the hospital field. It had been the centerpiece of our fiscal year 1984 legislative package.

We have also proposed to provide catastrophic coverage to protect our enrollees from the financial burden of a severe illness while at the same time restructuring cost-sharing principles to encourage cost awareness.

In addition, we want to create opportunities for beneficiaries to be able to choose among various private health plans through a voluntary voucher program.

Our medicaid proposals also include several initiatives that are designed to stimulate more cost-conscious behavior by beneficiaries, to maintain incentives to reduce program growth at the State level, and to improve the efficiency of program operation.

So, in summary, coupled with the President's proposal to limit the tax subsidy on high-cost private health plan, this particular budget calls for all segments of the health care system to work in unison to control costs.

Moving to the highlights of our appropriation request, Mr. Chairman, the 1984 budget represents an increase of $8.9 billion, or roughly 12 percent, over 1983. Our total 1984 budget is $85.6 billion. Of that, the appropriation request is $38.2 billion, with $1 billion transferred from the medicare trust fund.

The grants to the States for medicaid request is $20.7 billion.

Our budget estimate does assume passage of the administration's legislative proposals, and that includes the extension of the reduction in the Federal payments at the 3-percent level, mandatory cost sharing by medicaid beneficiaries, and improvements in our third-party liability collections.

The 1981 Reconciliation Act and the 1982 Tax Act have, we believe, significantly enhanced the States' ability to manage and control their medicaid programs through the use of waivers. A more extensive description of the waivers is included in the complete description of our budget request.

Payments to the health care trust fund total $17.3 billion, an increase of $1.9 billion over fiscal year 1983. Of this amount, $16.3 billion represents the Federal match to the supplementary medical insurance trust fund.

As a result of the Social Security Amendments in 1983, our request will have to be increased by $379 million in order to recognize $519 million for increased Federal supplemental medical insurance payments and a decrease of $140 million for military service credits.

PROGRAM MANAGEMENT

In terms of our program management account, we are requesting $1.1 billion in this area. That represents $83 million in budget authority and $1 billion that would be transferred from the medicare trust funds.

These funds support a number of activities.

RESEARCH

First of all, in the research area, we are requesting $30 million. This is the same level of funding as we had for 1982 and for 1983. It includes projects that support priorities that were established in 1982 and 1983 in the area of health care delivery and competition as well as projects which focus on program savings. Due to the Social Security Amendments of 1983, we have a large number of projects relating to prospective payment that will need to be integrated into the budget.

I think it is important to keep the level of funding in the research area at the maximum, since the return on investment in research and demonstration clearly has been proven. We have estimated savings of at least $2 billion in fiscal year 1984 as a result of past medicare and medicaid research.

MEDICARE CONTRACTORS

In the medicare contracting area, we're requesting $837 million. That's a net increase of $17 million over the fiscal year 1983 continuing resolution. That does include the supplemental $45 million that was authorized by the Tax Equity and Fiscal Responsibility Act of 1982 for audit and medical review. It is exclusive, however, of a workload contingency fund.

The majority of that $837 million budget will go to pay the essential claims processing function, but about 10 percent of it is set aside for payment safeguard activities which will result in medicare program savings. The fiscal year 1984 request reflects our continuing resolve to modify contractor operations in order to achieve greater efficiency and economy in the system.

STATE SURVEY AND CERTIFICATION

For State survey and certification, we are requesting $73 million. That is broken down into $38 million for medicare surveys and $35 million for medicaid.

END STAGE RENAL DISEASE NETWORKS

In the ESRD networks, there's a $5 million budget request. However, through a legislative proposal, we are requesting termination of this particular program due to the ineffectiveness of the networks.

PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS (PSRO)/PEER REVIEW ORGANIZATIONS (PRO)

In the PSRO/PRO area, there has been no funding requested. It is our belief that the prospective payment system would obviate the need for this type of a program. However, that budget was requested and developed prior to congressional passage of the Social Security Amendments in 1983, which do require that hospitals have contracts with the PRO's in order to be eligible for medicare reimbursement.

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Thus, we are reassessing the budget in this area, and we will advise you of those changes.

As you know, Congress just passed the Social Security Amendments of 1983 and we're still trying to understand more precisely what the act's intent is regarding PRO's.

ADMINISTRATIVE COSTS

We are requesting $201 million for our operating costs. This represents a net funding increase of $7 million, or a 4-percent increase over the fiscal year 1983 continuing resolution level. It does reflect a decrease of 256 authorized permanent positions, a 6-percent reduction.

We will do this through the elimination of duplicative and noncritical functions.

This effort clearly demonstrates our commitment to the President's objective of staffing the agency at the minimum level in order to achieve the most efficient and effective operation of our programs.

That, Mr. Chairman, is the summary of my remarks. I'll be happy to answer your questions.

Senator WEICKER. Thank you very much, Dr. Davis.

Senator PROXMIRE. Dr. Davis, I can't tell you how much I appreciate your statement, particularly your opening remarks.

INCREASED HEALTH CARE COSTS

This medicare/medicaid budget, particularly medicare, has just exploded out of sight, as you know and said so well.

I notice that in the first full year of medicaid, the cost of the program was $3.4 billion. Last year the cost was $50.7 billion and there is no indication of that cost growth slowing down—none.

When I look at the components of the Consumer Price Index, I notice that food costs have been leveling off, or dropping in some cases. The cost of gasoline and energy generally has been down. The cost of other items has been increasing much less than in the past, but not health services. Health is the one thing that goes up relentlessly, month after month after month.

And as a matter of fact, the way I've projected it, within 15 years, which isn't very long, the cost of medicare will be greater than the entire Federal budget is today.

We just have to have the most decisive kind of action to keep this program under control.

Now, there's nothing that's more important to our people than good health. And I think the greatest profession in the world is medicine. My father was a doctor and my son-in-law is a doctor. I think it's a marvelous profession.

But somehow we have to blow the whistle. Although I think that your analysis is very good, I'm concerned that there's not enough muscle in your recommendations to hold medicare costs down.

PSRO/PRO ELIMINATION

In fact, as I understand it, you have said something about eliminating peer review organizations or at least reducing funding for them?

Dr. DAVIS. In our initial budget submission, we did not request funding for the PSRO/PRO, because it was our belief that, under the prospective payment system, peer review would be better accomplished within the individual hospital. Prospective payment provides an incentive for hospitals to stay within their fixed payment, and as a result, hospitals would want to internally initiate their own peer review systems.

However, when they passed the legislation, Congress spoke about the necessity for having a Federal Peer Review Organization. As you know, the legislation was just enacted 2 weeks ago. We are now trying to clarify how we will move on that particular area.

I think it's very clear that there is an intent by Congress to have a PRO. It's simply a matter of how we move from where we are today, Senator, to where we need to go with the PRO's.

HEALTH SERVICE AGENCIES

Senator PROXMIRE. How about the health service agencies?

Dr. DAVIS. They're not within my jurisdiction.

Senator PROXMIRE. They may not be within your jurisdiction, but they certainly affect the cost of the program, don't they? They're intended to.

Dr. DAVIS. They're intended to.

I think it's debatable, in terms of what their effectiveness has been.

PROSPECTIVE PAYMENT

Senator PROXMIRE. It seems to me that these are the only two medical cost watchdog agencies we have. I would hope that if we do displace them we make sure that we substitute a mechanism that is going to be far more effective than they've been.

Let me ask you——

Mr. SCOTT. Senator, could I respond——

Senator PROXMIRE. Yes.

Mr. SCOTT [continuing]. Just a second——

Senator PROXMIRE. Certainly.

Mr. SCOTT [continuing]. On the health systems agencies?

With respect to payment, we have dramatically changed the incentives that hospital administrators have in the acquisition of new services and new pieces of equipment.

In the past, under retrospective cost-based reimbursement, whatever they bought, we went ahead and paid our fair—our proportional—share of.

But now, under prospective payment, with a system working off a fixed base, for example the 1982 cost, investments in new, exotic pieces of equipment are not reflected in that base.

And so the administrator now has to take a look at that—if he buys a new piece of equipment or if he starts a new project, he must consider his cost in relation to his reimbursement.

Prospective payment will result in no reduction in hospital cost inflation in fiscal year 1984 and fiscal year 1985 beyond that already reflected in the budget, since the legislation requires that prospective payment be budget neutral. After fiscal year 1985, prospective payment levels will be determined by the Secretary of HHS, taking into consideration in the recommendations of a commission of experts. We do anticipate that the movement from cost based reimbursement to prospective payment will have a positive effect on increasing hospital efficiency and thus reduce inflation in this sector.

Senator PROXMIRE. What reduction in the rate of medical care cost inflation do you expect to flow from this kind of action?

Dr. DAVIS. The prospective payment?

Senator PROXMIRE. Yes.

Dr. DAVIS. It is budget neutral in terms of its application. We expect that what savings we had in TEFRA would continue.

I share your concern for the rapid spiral in these costs.

It's interesting to recognize that under the hospital insurance part of medicare, about 56 percent of the projected increase is due to inflation itself, and another 32 percent is due to increases in the intensity and the utilization of services. That leaves approximately 11 percent that is due to the growth in the number of beneficiaries.

It's in the areas of control of the inflation, and the control of the utilization and intensity that we have to focus.

Senator PROXMIRE. I just wonder if the prospective payment system, as passed by the Congress, can do that much of a job. I guess this system began at Yale, didn't it? Wasn't that one of the——

Dr. DAVIS. Yale University developed this.

Senator PROXMIRE. And they've done a good job up there.

But I wonder if even Yale would claim that it would be more than somewhat helpful, but quite limited.

Maybe you can lower the rate of inflation slightly, but I wouldn't think that you could expect the prospective payment system to do that much more.

BUDGET PROPOSALS TO CONTROL COSTS

Dr. DAVIS. Well, Senator, we don't believe that prospective reimbursement is the total answer to all of the problems with medicare. That is why we have put forward a number of proposals, such as restructuring the part A benefit package. We need to take a number of approaches to controlling costs because the hospital insurance trust fund is vulnerable at this point in time.

It seems to me that we really have to look at the entire system from the point of view of not only reimbursement reform, but also the idea of reforms of our system of third party payment and the need for increased beneficiary cost consciousness. Finally, we have to examine the whole area of alternatives to institutional or hospital care.

As you know, ambulatory surgical centers have recently come into operation. Clearly, for those kinds of procedures that can be adequately and safely done in an ambulatory setting, we believe they can deliver care at a lower cost.

So, we must look at all three of these areas.

MEDICAID PROGRAM IN WISCONSIN AND ILLINOIS

Senator PROXMIRE. I have a couple of other questions. But I would like to say that I was particularly impressed by one of the things that my dad used to tell me. He had a good practice in a prosperous suburb of Chicago—but he used to tell me that he wouldn't send a bill to about 30 percent of his patients because he knew they couldn't pay it. Then he would trim his bill for others. And his charges were just a joke compared to what they are now. He'd charge $1 for a office call, $5 for a house call, and $25 for delivering a baby.

Even allowing fully for inflation, doctors in those times charged less, because people paid the bills, instead of institutions. The bills weren't paid by medicare, medicaid, or Prudential Life Insurance, which pay so many of our bills now. Currently 90 percent of medical costs are paid not by individuals but by some kind of an institution.

Somehow, it seems to me, we have to come to grips with that problem. It's hard to do it without placing a burden on individual people who are sick. But we have to think about the problem at least, and consider how we can work some cost incentives in. Maybe people could pay a larger portion of the cost. I guess Secretary Schweicker indicated that he favored that kind of thing.

I think getting into this area is going to be difficult, but I think we have to push this kind of approach.

Let me just ask you this. I was interested to note that on page 23 of your justifications you indicated that Wisconsin and Illinois are exceptions to the rule that most of the States with the largest medicaid programs are expecting double-digit inflation in hospital prices to continue.

We're proud of our medicaid program in Wisconsin. It's a Cadillac program—one of the best. Wisconsin projected inflation to be at 7 and 6 percent in fiscal year 1983 and fiscal year 1984, respectively. Illinois expects to hold price increases to 2 percent in fiscal year 1983.

What makes Wisconsin and Illinois exceptions to the rule?

Dr. DAVIS. It depends totally upon the management of the system in the State medicaid program, the types of activities that they decide to do, the numbers of services that they cover. As you know, some programs cover more optional services than others.

It also reflects the decision of some States to use waivers—waivered services in the home and community-based area.

The Wisconsin assumption was, according to the justification accompanying the State's estimate, based upon economic assumptions supplied by a private firm. It was not clear whether this low rate was the net rate after actions the State was proposing to take to control costs or it was the rate projected with no restraining action on the part of the

State. Illinois expected to actively control hospital cost increases to the 2-percent rate. The justification accompanying the State's estimate was, however, not specific as to the means of achieving that rate.

Senator PROXMIRE. Have you analyzed the successful programs to see what they have in common and what lessons can be learned by others?

Dr. DAVIS. We have not specifically targeted the two States that you mentioned, but we consistently do follow State activities.

Senator PROXMIRE. Wouldn't that be useful?

Dr. DAVIS. Yes, indeed.

Senator PROXMIRE. Do the States communicate? Do they get a——

Dr. DAVIS. We have contracts to evaluate our demonstration programs, some of which are State based.

Also, we do have a yearly survey of the new activities or program areas that are being added or deleted.

In addition, we do have, twice a year, State medicaid agency conferences. We find that's a very helpful place to learn more specifically States' new activities, including those which are, perhaps, cost effective.

Mr. SCOTT. In addition, Senator, many of the dollars, of course, are put back in the States under very complicated reimbursement systems.

And we have an ongoing program where we look at the State nursing home reimbursement activities and try to develop some good practices, the best practices, that we can share with other States.

So, we're helping them in that very detailed, very sophisticated area of reimbursement, to share what good lessons have been learned with the different kinds of systems.

INCREASED COST IN MEDICAID

Senator PROXMIRE. Now, if the table on page 24 of your justifications is correct, there's a startling figure that stands out: Physicians' costs in Wisconsin under the medicaid program will increase by 54 percent between 1983 and 1984.

What's the reason for that mammoth 1-year increase?

Dr. DAVIS. I will have to submit the exact reason for the record, Senator. In some States, the payment for physicians has been frozen at a very low level, and individual States have begun to look at that in an effort to guarantee that there are more physicians that are willing to take assignment and to work with these individual patients. But I can't speak to whether or not that is the reason.

We will clarify that for the record.

Senator PROXMIRE. I'd appreciate that very much.

[The information follows:]

The physician cost increase in Wisconsin between 1983 and 1984 is 5.4 percent. The 54 percent reflected in the table on page 24 is a typographical error. The 5.4-percent increase factor is consistent with the low assumptions about price increases in other services.

Senator PROXMIRE. Thank you, Mr. Chairman.

I have some other questions that I'll submit for the record.

Senator WEICKER. Thank you, Senator Proxmire.

I am interested in your comments and also those of Dr. Davis.

Let's assume, Dr. Davis, that you have cancer. What portion of the process available to cancer patients would you do without: That which relates to chemotherapy, that which relates to radiation, the hospital care, the research? What portion would you do without?

Dr. DAVIS. Well, frankly, I would hope that, using our new authority that we are planning on implementing this fall for the hospice benefit, I wouldn't need to do without any, but I think I understand where you are coming from, Senator. Clearly most of our health dollars are being spent in the last 6 months of life. We do believe that through the hospice movement, our enrollees can receive adequate necessary care, without the drawbacks of institutionalization where the individual perhaps is receiving a level of acute care they may not wish to have.

Senator WEICKER. Well, my question really goes to a broader perspective than just the hospice movement. I think I am fairly well acquainted with it, since my sister started the hospice movement in Arizona. I was talking about the whole spectrum, when you are first notified by your doctor that you have cancer. What are you going to do without?

The point that I am trying to make, Dr. Davis is that I am not sitting here as a Senator designating what my constitutents should have. It is an entirely human reaction to want to live and to have the best possible care. And I don't know how that will ever be achieved cheaply, in terms of medical science.

I watch the television. As of late, I have seen quite a few programs that indicate the plight of those that don't have any insurance. Nobody wants them. I am sure the whole spectrum of care is not available to them, even under our present system. I am not impressed by the fact that what the figure cited—it started off at $3.4 billion—is now $3.7 billion. I am probably interested in the per patient cost, that might be something, but the total dollars don't mean anything to me.

We know from the development of hearings over the past several days that there are 22 to 25 million people out there that have no coverage and, therefore, really aren't getting much in the way of care.

And if there are some doctors that are ripping people off, nail them. I have no problem with that. But I don't think we've reached the millennium as far as the care of our citizenry is concerned, by a long shot. I think there are a hell of a lot of people out there that are not getting the care that you would demand and I would demand. And I don't think that our economic status in life should determine what it is that we are going to get in terms of assistance to our particular ailments.

So I just wanted to get another philosophical point of view on the table here; I won't be satisfied until the best possible care is available to every one of the citizens in this country. And if there are abuses, then let's hit the abuses, but the concept that we started out with, I

think is as valid today as it was then. And we are a long shot from even delivering on that, as we have 22 to 25 million out there uncovered.

Have you watched these shows lately? I mean now the whole hospital system is going into the for-profit business, and boy, are they making profits. What about the other hospitals that receive those that can't pay. Do you think that's right? What about the patients? These hospitals just aren't staffed to go ahead and give the care that they should. Everything is being dumped on them. And what do we do?

Dr. DAVIS. One of the things we can do is to look at alternatives to hospital care. Clearly, the cost of hospital care has been rising the fastest. It is the one that has the largest price tag. I know that we could identify occasions when care can appropriately be given either in an outpatient clinic or in another setting which would reduce overall costs without reducing the quality of care. Home health care is also part of a whole variety of options that need to be looked at, alternative ways whereby we can deliver care safely and effectively, but at a lower price. And that's what I meant by saying reimbursement reform is only one of the areas of reform that we have to look at. Another one is alternative delivery systems. Health maintenance organizations are a good example. We know that they deliver care effectively, but at a lower cost because they are careful in terms of utilization of hospital days.

So we are trying to look at several alternatives at the same time, because there is no single solution.

HOSPICE BUDGET

Senator WEICKER. What is the administration's proposal in this budget relative to the moneys available to the hospice movements throughout the country? What are they proposing in the way of a budgetary allowance?

Dr. DAVIS. It's in the law, and we are in the process now of implementing it with regulations. I believe that the statute indicates that it must be effective as of November 1.

Senator WEICKER. What kind of money is going to be asked for?

Mr. FISCHER. Senator, the estimate for fiscal year 1984 is approximately $70 million.

Senator WEICKER. $70 million in 1984?

Mr. FISCHER. Yes, sir.

Senator WEICKER. And that's going to take care of the hospice program?

Mr. FISCHER. That's our estimate. Of course, it is a startup. It reflects our estimate of how many hospices will participate and how rapidly they will come in. The final regulations will establish the specific criteria under which medicare coverage for the hospice benefit would be applied.

Dr. DAVIS. Since you indicated that your sister has been very active in that movement, I am sure you are familiar with the fact that the major accomplishment is the alleviation of pain and keeping the individual comfortable. It is not intended to be crisis management, the

major focus tends to be on care in the home or in a hospice-type situation.

Senator WEICKER. I am well aware of that.

Dr. DAVIS. That's why the costs are less.

Senator WEICKER. I am well aware of that, but I am also well aware of the fact that Mary Audrey happens to be a registered nurse, and she doesn't charge for her services, and, you know, she is giving 5 days, 6 days a week, more or less a portion of every day out on the road. And I don't know what's going to happen, in the sense that not everybody can afford to do that. Don't kid yourself. This is, indeed, when you cite costs to me, a very personal matter, as you know. It is a one-on-one deal, whether there is a doctor involved or not. And if we are going to start to pay for that, that's not going to be inexpensive at all. It's a far more preferable setting. There is no question about that, I think we would all agree.

But I don't want to give the impression that hospice care is necessarily cheap. It has been cheap, because of the dedication of a large number of volunteers who have brought that concept to this country. Now as to whether or not that continues once this becomes a part of a federally-financed Federal program, I think is going to be very interesting to see. I dare say that some of the costs are ridiculous. Mary Audrey is not alone. She started to build the one in Phoenix, Ariz. And I would say that probably maybe 20 percent of the staff, 25 percent is paid. And it is an enormous amount of volunteer work that goes into this movement. And I don't think that $70 million is going to turn the trick at all.

But I don't mean to get into a thing about hospices. All I am saying is that these alternatives also have a cost that attaches to them.

Dr. DAVIS. Senator, may I just comment. By 1988, we have estimated that the hospice cost would be about $280 million. But one of the intents that we do have——

Senator WEICKER. By what now? By 19——

Dr. DAVIS. 1988. One of the features that has been, we think, a very important part of the hospice movement is the volunteer aspect. And we do have a requirement that we will probably have in our regulation to try to keep that kind of volunteer effort moving forward, because I think it is a very valuable and very important part of the movement.

COST OF MEDICAL CARE

Senator WEICKER. I am not arguing to the fact that our medical services or the delivery system should stay the same. It shouldn't. Obviously, technology has improved in that area as well in the formulation of drugs and surgery techniques and all the rest. Whether it is hospice or whether it is home care that Senator Hatch has advocated, I mean there are many different ways, and we should try them, but I am afraid that you are not going to get away from the human desire to live, and when you are hurt, to get the best possible treatment.

Now you are not going to get away from it, and it will never be cheap, but I am not going to go ahead and try to create the impression that these costs are going to go down. They have gone up spectacularly, because this was an area of social need that we never addressed as a Government before. We are addressing it now. And it is expensive.

I remember that great line, whether you like it or not. It's probably one of the most—not prophetic lines, but accurate descriptions of the attitudes. Did you ever see that movie that was based on the novel by Robin Cook, "Coma"? Did anybody see "Coma"? And remember when finally the head of the hospital was discovered as having been involved in the business of, in effect, killing patients to—well, not killing them, but putting them in a coma, so that they could later be used for the delivery of vital organs to those that were dying. And he was discovered in the scheme, and he was justifying his rather murderous intent. And he makes this statement, which is true. He said, "Hospitals are the cathedrals of our time."

Now that's true. That's what they have become. And probably to the extent that they are no more the complete answer than the cathedrals were in their time. But you can't help but see the misery that is out there, and that it is unattended, and feel any other way than the job is anything but done. And that's why I speak as I do, regardless of the cost that's attendant to this. And certainly it is a staggering cost.

MEDICAID BUDGET ESTIMATES

So the committee is interested in what assumptions went into building your fiscal year 1984 medicaid request.

Now in fiscal year 1983, your appropriation was $19.3 billion, but in fiscal year 1984, your comparable budget request is a little over $21 billion.

How do you reach that number? What drives it?

Dr. DAVIS. We used the November estimate, Senator. I would like to ask Mr. Fischer if he would comment more specifically on this.

Mr. FISCHER. Senator, we receive estimates from the States. We have found historically that their estimates are the most accurate in determining the costs of the program. We then adjust those estimates to include costs or savings related to legislative proposals or regulatory changes which the States would not have had in their estimates. Specifically, we decreased the States estimates by $568 million to fully reflect the impact of the Reconciliation Act of 1981 and by $275 million to fully reflect the impact of the Tax Equity Act of 1982. In addition, we reduced the estimates to take into consideration the effects of family responsibility in long-term care and furthering third-party liability collection efforts.

The total increase of 1984 over 1983 is 9 percent. It does reflect a considerably lower increase than in the past, which in the previous 5 years had averaged 15 percent. I think it is a reflection primarily of the States utilizing the flexibility the Congress has enacted to control the cost of their programs by using alternative settings and by achieving greater efficiency in the way they operate.

MEDICAID SAVINGS ESTIMATES

Senator WEICKER. We note that as part of your request, you are assuming savings of some $400 million as the result of recent changes in law, such as allowing States to impose copayments for care and to put liens on the property of those confined to nursing homes. You also hope to recoup savings under some new policy directives.

To what extent are your assumed savings optimistic?

Mr. FISCHER. Sir, the savings that we have in the budget have been estimated by actuaries. Actuaries generally are rather conservative in their estimates and have a history of accuracy. In the medicaid area, it is doubly difficult for the actuaries to estimate, because of the difficulty in anticipating State behavior and because the majority of these changes are providing additional flexibility for the State. Therefore, the projections must include estimates as to what extent each State will use the flexibility and make a change that we propose.

Senator WEICKER. Let's take one example. You apparently hope to recover about $89.5 million from the health insurance of absent fathers who are under court order to pay child support. Now that's a new program.

Do you expect it will begin producing results immediately—and to the full extent you hope?

Mr. FISCHER. Yes, sir. That's our estimate. That particular estimate is made up of the assumed recovery, which is well in excess of that net of the cost of actually administering the program.

Senator WEICKER. So you think you are going to get $90 million in fiscal year 1984?

Dr. DAVIS. We have a model program now, working with three States, looking at this particular area. So the implementation will be made easier, because of the model program.

Senator WEICKER. But this will be the first time that you have tried it? In other words, you are doing this strictly on a projection, not on experience?

Dr. DAVIS. Our actuaries always work on projections. And again, as Mr. Fischer said, the actuaries tend to be very conservative in their estimates.

Senator WEICKER. I used to be a lawyer. Have you ever tried to chase these types down? And whether you can do it in 1 year's time? No way.

Mr. FISCHER. We have substantial experience with the Office of Child Support Enforcement, which has, of course, been in existence for a number of years within the Department, and has pursued recoveries primarily to offset the cost of AFDC. Our proposal, specifically, would require that those agencies share information with the medicaid agency. The medicaid agencies historically have had a major program and major effort in actually recovering from other parties that should be paying. This is an increase to it, but by no means a new program. The States have been doing this kind of activity for a number of years, and many of them quite effectively.

Senator WEICKER. Well, we'll see, next year. I certainly hope he's right. [Laughter.]

LONG-TERM CARE—FAMILY RESPONSIBILITY

Another example: You hope to recapture net savings of $35 million from getting adult children to contribute to the nursing home support of their indigent parents. This is based, we gather, on the States passing legislation to implement the concept—legislation that could be controversial.

Again, isn't there more optimism than justified that you'll get the savings?

Dr. DAVIS. The National Governors' Association and the American Public Welfare Association also indicated to us that there are about 10 or 11 States that had an interest in moving in this area. Our estimate is based upon that.

Senator WEICKER. There are 21 States who had an interest?

Dr. DAVIS. Ten or 11 States that have been identified as having an interest.

Senator WEICKER. Ten or 11 who have an interest?

Dr. DAVIS. Yes.

Senator WEICKER. How may have passed the legislation?

Dr. DAVIS. To my knowledge, two have passed it. There are several States that are in debate now in their State legislatures and others are in the beginning formulative phases.

Senator WEICKER. What if they don't materialize? This $35 million doesn't materialize?

Dr. DAVIS. If it does not materialize and the $35 million is not collected, then we will be looking at other savings.

Senator WEICKER. Is counsel correct when he says it is going to cost $81 million to get this $35 million?

Dr. DAVIS. $116 million that would be collected. This would be offset with $80 million needed to administer the program.

Senator WEICKER. Then why is this a good program from a budgetary point of view?

Dr. DAVIS. It is more than just a budgetary point of view. What we are saying is, if the State has a general rule of applicability, and they want to have this as a mechanism, then we are not going to stand in their way for that, something the individual State has determined. Also, those dollars, Senator, are reflective of the Federal dollars, so that there is an additional amount that would be saved from the States. So you're roughly talking about a $70 million savings.

MANDATORY COPAYMENTS

Senator WEICKER. The administration has been proposing legislation to shift from optional to mandatory copayments from medicaid beneficiaries seeking nonemergency care. These would be nominal copayments in the range of $1 to $2.

Since the provision for "optional" copayments was started with the current fiscal year, don't you think it might behoove us to have experience in hand before seeking a mandatory requirement?

Dr. DAVIS. A number of the States have been interested in copayments. And when the TEFRA was passed, while it allowed for some funding in the copayment areas that had not been allowed before, it did make exceptions for certain individuals and services. A number of the States have found that they lost some of their flexibility. In fact, a few of the States have now stopped using copayments, because they found that it was administratively difficult for them to handle under that type of guideline.

Senator WEICKER. To what extent will any of your projected savings accrue, because beneficiaries will not use medicaid in order to avoid the copayments?

Dr. DAVIS. Under the Tax Act provisions, we estimate a savings of roughly $36 million. It is due to what we call deferral in utilization.

Mr. FISCHER. Senator, within the savings estimate of $249 million from the proposal presently under consideration, we assume that $100 million—and this is the actuaries who assume this—$100 million would actually be collected from beneficiaries through those nominal copayments. And the assumption was that $149 million would actually be saved as a result of reduced utilization of services, due to the copayment.

Senator WEICKER. Now that's a little troubling. Of people who are not going, or savings of people who are not going, to get care because they have to pay a copayment, you estimate a savings of $149 million?

Dr. DAVIS. We may need to submit this for clarification for the record. In estimating the mandatory copayments, we had two figures. One was the figure that was related to the total savings under the copayment and the other was the additional savings, as a result of moving from this year's TEFRA to the next year's mandatory copayment. If we may, we would like to elaborate on that for the record.

Senator WEICKER. I think you should. If you would please clarify that for the record, I would appreciate it.

Dr. DAVIS. Yes, we will.

[The information follows:]

The estimate for the mandatory copayment assumed that for the $249 million saved in fiscal year 1984 that $100 million will be from the offsetting collection of the copayments and $149 million will be from the reduced utilization of inappropriate services. The TEFRA optional copayment proposal is expected to save $90 million in fiscal year 1984, of which $54 million was assumed to be from the offsetting collection of the copayments and $36 million was attributed to reduced utilization.

MEDICARE CONTRACTOR BUDGET

Senator WEICKER. Senator Proxmire?

Senator PROXMIRE. Thank you, Mr. Chairman.

In the first place, before I forget, Dr. Davis, I did want to compliment you on behalf of Senator Inouye for your willingness to look at the use of nurse practitioners to save costs. He was very happy about

that. He also appreciated your decision to look at the relationship between mental health and physical health care costs. He wanted to be sure to let you know how delighted he was that you were taking those steps.

On page 95 of your justifications, you say, "The medicare adminstrative reform initiative represents a systematic and comprehensive review of the entire body of regulations, procedural instructions, and performance standards governing contractor operations; it has already saved over $63 million in fiscal year 1982 and will continue to provide a basis for further administrative savings in fiscal years 1983 and 1984.

Now since estimated contractor funding levels in 1982 were about $704 million and actual costs were $711 million or $7 million higher, what does the $63 million in savings represent, and what base amount should it to be deducted from?

Mr. FISCHER. Senator, the $63 million savings that we achieved in 1982, which is referred to there, represented our efforts to live within the budget that we had, which, as you indicated, ended up at $711 million. That represented many changes that we made in our operations. Had we not changed those operations, the way we were operating in the past, we would have required a supplemental in fiscal year 1982. And that's what that intends to convey.

Dr. DAVIS. Senator, Mr. Scott, perhaps, can elaborate on exactly what kinds of major——

Senator PROXMIRE. That would have been a big increase in your base then, wouldn't it? The base would have gone up from an actual level of $691 million in fiscal year 1981.

Mr. FISCHER. Yes, sir. That reflects two things, I think. The medicare contractor budget was held essentially flat from 1981 to 1982, and we lived with that in 1982 by achieving some of these savings, as you indicate. In addition, as you look at the 1983 level, that reflects the additional $45 million congressionally enacted and required by the Tax Equity and Fiscal Responsibility Act of 1982 to be applied to audits and medical review.

Senator PROXMIRE. Well, from a cold, hard account viewpoint, the medicare administrative reform initiative didn't really reduce spending or make a net saving. You reduced the rate of increase that you otherwise would have had.

Mr. FISCHER. Yes, sir.

Dr. DAVIS. Yes; we would have had to come back and ask for additional funding, if we had not achieved those savings.

Mr. SCOTT. It was a very healthy exercise for us, Senator, because it made us sit back and look very carefully at the way we managed the contractor budget, and we found that there were some things we were doing that just simply were not appropriate. We were imposing some reporting and paperwork burdens on the contractors that were not yielding any program value. So through that—it's a very complicated process—we have been able to remove a lot of that burden and make the process work a little bit better, and also automate more of the

process. So the exercise has left us with an improved contractor operation.

MEDICARE CONTRACTOR PRODUCTIVITY

Senator PROXMIRE. Well, I see that you were able to cap contractor costs that way for 1 year, but then they bounced right back up again. In 1983 you project a budget of $820 million, right? So the $63 million was a 1-year saving. You estimate contractor costs are going to be $837 million in 1984, but we will have to wait and see.

Dr. DAVIS. Senator, those savings will be carried through, because otherwise we would have had to increase our base. Those are additional increases that we now have been able to keep out of the base by that kind of a reduction.

I think that one of the things that we are trying very diligently to do now is to apply some of this year's funding toward productivity investments in the areas of automated billing, to develop more automated claims processing capability. A new system we are implementing in this area is what we call a uniform bill. These are all areas where we're trying to invest money now that are going to give us savings that will accrue in later years. We think it is very important to move quickly into an automated billing mode.

CONTRACTOR BUDGET INCREASE

Senator PROXMIRE. Well, let me put it a little different way. Although medicare contractor costs increased by about $20 million, approximately 3 percent, between 1981 and 1982, they are scheduled to increase by 15.3 percent, a whopping $109 million between 1982 and 1983. Doesn't that indicate that your medicare administrative reform initiative has failed in its objective?

Dr. DAVIS. No; I believe, as Mr. Fischer said earlier, that represents two things. First, we normally have seen an increase of about 10 million a year in the number of claims that need to be processed. And second, if you add that with about a 5-percent increase——

Senator PROXMIRE. Was there, in fact, an increase of 10 percent in claims between 1982 and 1983?

Dr. DAVIS. Yes; our preliminary 1983 actual experience projects an increase in workload of 10 percent.

Senator PROXMIRE. You only show a 2-percent increase in contractor costs in 1984?

Dr. DAVIS. It's due to the fact that we are also achieving internal savings through our reforms and looking at the system, as we had indicated earlier.

Senator PROXMIRE. But why couldn't you achieve those savings in 1983?

Dr. DAVIS. We have had an ongoing program since 1981, looking at the way that we can achieve internal savings. The $63 million that was achieved that year is continuing on. Otherwise we would have had to ask for a larger increase.

I think another point to remember is that Congress did indicate that they wished us to have $45 million new dollars in the area of auditing and medical review. And the increase for fiscal year 1984 includes that $45 million. That represents part of the increase——

AUDIT AND MEDICAL REVIEW ACTIVITIES

Senator PROXMIRE. As you say, once again this year you are requesting the transfer of $45 million out of the medicare trust fund under section 118 of the Tax Equity and Fiscal Responsibility Act of 1982 to carry out provider cost audits and reviews of medical necessity.

The Congressional Budget Office has estimated the expenditure of $45 million for 3 years under this authority will save $730 million in unnecessary medical care costs.

Can you tell us how much in total you've budgeted for medical necessity reviews this year and next year and also indicate how much you obligated for this purpose last year?

Mr. SCOTT. I'm not sure I've got all of the specific details. Of the $45 million in 1984, we are going to use $7 million of that to do part A medical reviews. These are the hospital sites. We generally are shooting for a 3 to 1 return. For every dollar we invest in part A medical review, we expect contractors to give us back $3 in program savings. $15 million of that will go to a part B review, the reviews for the physicians and the suppliers. In that area, we are expecting about a 5 to 1 return.

We estimate that our entire payment safeguard activities, which are medical reviews for both part A and part B plus our audit activities, will save $577 million in program money in 1984.

Senator PROXMIRE. Why wouldn't it be cost effective to increase funding for medical necessity reviews, if they produce this kind of savings.

Mr. SCOTT. There is an operational consideration. In fact, we talked about it last night, as we're looking to move into prospective payment. There is a limit--I guess a sliding scale. You reach a point of diminishing returns somewhere in that process, when the budgets, and some of the activities we get involved in, are trying to focus the review on particular kinds of problem areas.

Senator PROXMIRE. Will you submit that sliding scale for the record.

Mr. SCOTT. We will; yes, sir.

[The information follows:]

Health Care Financing Administration generally expects an overall return of $4 for every $1 invested in payment safeguards. The return on the first dollars invested will be the highest, because when relatively few dollars are available, they tend to be utilized on the most obvious cases of excess utilization and inflated cost reports. As more dollars are employed in payment safeguards, the difficulty of identifying unnecessary services and nonallowable costs becomes greater, so relatively greater administrative costs are incurred to achieve additional program savings. Because so many variables are involved (inflation, productivity, contractor personnel changes, et cetera), a single sliding scale does not exist for measuring return on investment for various safeguard activities. In order to maximize the return on HCFA's investment in program safeguards, we are allowing the medicare contractors to design the specifics of their medical review and utilization review activities (MR/UR) to reflect the utilization patterns in their local areas. Data on actual returns on investment for each contractor will be gathered and evaluated.

Senator PROXMIRE. But you're satisfied that if you invested more, you wouldn't continue to get a bigger return than the amount invested?

Mr. SCOTT. With these succeeding dollars, our expectations are——

Senator PROXMIRE. That's a marvelous return, 5 to 1.

Mr. SCOTT. Not a bad return at all.

Senator PROXMIRE. On September 30, the Inspector General made a tentative finding that more efficient procurement of pacemakers could result in annual medicare savings of over $64 million. Auditors compared prices for 2,804 pacemakers bought by 25 hospitals in 10 States for medicaid patients with prices available to Federal agencies under GSA's multiple award Federal supply schedule.

Most of the procurements under the schedule were for VA hospitals. The auditors found that under medicare, the hospitals paid an average of $591 more than GSA paid under the supply schedule contracts.

What arrangements have you made to obtain a more favorable price for pacemakers?

Dr. DAVIS. We looked at that particular issue and, in fact, I chaired the task force on the pacemakers for the Secretary within the Department. And one of the things that we are doing is looking at the issuance of new guidances which clarifies who should, indeed, receive a pacemaker and who should not.

In terms of the procurement of pacemakers, we believe that the passage of the new legislation for the prospective payment system, where they have fixed payment, precludes our necessity to work in this area, because each hospital will, in and of itself, want to negotiate for the lowest price. This is because we now include the price of the pacemaker within the prospective payment rate, and our rate is fixed. Thus, it is in the interest of the individual hospital to shop for the lowest price.

We know from our experience in New Jersey that this was the case. And in fact, we have anecdotal evidence that in New Jersey, once this was made public, that the individual institutions published a price list of what the prices were on the pacemakers, and that they——

Senator PROXMIRE. When you set a pacemaker price, is it comparable to the Inspector General's recommended price?

Dr. DAVIS. Our price for our DRG would include the price for the pacemaker.

Senator PROXMIRE. And would you expect the pacemaker component to be priced at the level the Inspector General recommended?

Dr. DAVIS. Well, we—no, I think that what we are saying is that Congress has now passed a prospectively fixed system. The Inspector General's report was really focused on when medicare was under a reasonable cost system, and hospitals passed the cost through to us. Because there now is a new payment mechanism, they can no longer pass every cost through to us. They have a fixed payment, and they must live within it.

However, we think there were other areas that he raised that are of significant interest to us. And I intend to pursue them. For example,

the issuance of new guidelines for the reimbursement for the monitoring of implanted pacemakers, is an area that we are looking into now. We have also just taken steps to modify our payment systems, so that we can check when a pacemaker is replaced. If, indeed, it is still under a warranty, our edit will kick that claim out of the system and refuse to make a payment. We found that in the past there were occasions when, because our systems were not able to catch it, we were paying for a second pacemaker.

So I think there are a number of things that we are moving forward on in the whole area of the pacemaker system.

KIDNEY DIALYSIS

Senator PROXMIRE. On January 21, the General Accounting Office issued a report on the kidney dialysis program that concluded requiring a purchase of necessary equipment by medicare users as an alternative to renting the equipment would save on the order of $20 per treatment. The report also found that in some cases medicare patients paid almost twice as much for supplies as the amount paid by some facilities.

The report concluded that medicare should be able to negotiate a supply price at least equal to the price the Veterans Administration pays and that medicare should require the purchase of equipment for patients dialyzing for prolonged periods.

What steps are you taking to implement those recommendations?

Dr. DAVIS. We are in the final stages of issuing a new regulation that addresses the payment. It will be a fixed payment system, which we believe obviates the necessity to look at this particular measure. Again, this kind of a report was initiated assuming a cost system. And we think that our new regulations, which are in final clearance at EOMB, will obviate that necessity and will hold down the cost.

Senator PROXMIRE. Thank you, Mr. Chairman.

Senator WEICKER. Thank you, Senator Proxmire.

THIRD-PARTY LIABILITY

Dr. Davis, you are proposing changes which require applicants for medicaid to assign private health insurance rights to the State medicaid agency. You estimate $6 million in savings.

What evidence do you have that the people who would be eligible for medicaid have much access to private or third-party health insurance coverage?

Dr. DAVIS. We have anecdotal evidence from discussions with many of our State medicaid directors that speak to some of these areas. We do a review each year of the medicaid State agencies, chiefly in the area of error rates. And we have determined that, in terms of the State's error rates, eligibility is one of the areas that they clearly do not do a good job in as well as the whole area of resources, and in particular, identifying third party resources. This is clearly an area in which they can do more. The savings do assume a 10-percent increase in the collection of the third-party payments from what they now are.

HOME AND COMMUNITY BASED WAIVERS

Senator WEICKER. The Reconciliation Act of 1981 allows the Secretary of HHS to grant waivers to the States to allow them to provide home care for the mentally retarded and thus avoid putting them in institutions.

What sort of services are provided, and how many States have taken advantage of this procedure?

Dr. DAVIS. Of the total number of home and community-based waivers, roughly 20 States have had approval for 22 community-based waivers for the mentally retarded. And that is a component of our total number of home and community-based service waivers. Many States have a home and community-based service waiver that applies specifically to the targeted mentally retarded and developmentally disabled, and other States have a more general one.

Senator WEICKER. How is the program coordinated with the Developmental Disabilities Act, both at Federal and State levels, to make certain the best care is provided?

Dr. DAVIS. It is my understanding that the developmentally disabled groups comment as the State is forming their request in the area of the waiver. The councils are involved frequently in initiating and planning along with the States in this area. As the waiver goes through our system, we do ask the Office of Human Development Services to review the applicability in this area. But there is no statutory relationship whatsoever.

Senator WEICKER. Counsel indicates to me that the number of developmentally disabled under waivers is less than 50,000. And that is out of a total of 4 million.

Dr. DAVIS. Senator, the States have had the ability to use the waiver now for roughly about 1½ years, and we find that we are getting increasing numbers of waiver requests, almost weekly. We will continue to see more. The States' initial intent, as they move in this area, is to designate selected areas of the State, work there, then they will try to expand, once they have learned how those resources can be structured best.

LIENS

Senator WEICKER. The Tax Act of 1982 provides States with new authority to impose liens on the homes and other property of medicaid patients who are likely to be confined in nursing homes for the remainder of their lives. And you are projecting savings of $60 million in fiscal year 1983 and $127 million in fiscal year 1984.

Is this again an actuarial projection——

Dr. DAVIS. Yes, it is, sir.

Senator WEICKER [continuing]. Or is this based on experience?

Dr. DAVIS. Yes.

Senator WEICKER. The law requires that those against whom liens will be placed will get a notice and opportunity for a hearing.

Now what you are suggesting here is that we haul them out of the nursing homes and produce them for the hearings? Is that it?

Dr. DAVIS. No; this, again, is a State flexibility option; that is they can impose a lien, but they must do so after notice and opportunity for a hearing.

Senator WEICKER. That's a great phrase, but it means one thing to you and me. You know, we can appear at the hearing, somebody else is sitting in the nursing home.

Dr. DAVIS. We had clearly specified that if the individual can have a reasonable opportunity to return home, the lien provision should not be used. It is only in those cases where there is the presumption that they cannot return home. And if, indeed, the individual does return home, then the lien is dissolved against him.

Senator, prior to the Tax Act a number of individuals would simply sell the property and the amount that was due to the State could not be collected from the sale of the property. The proceeds of the sale then went to some family member. And under TEFRA the State now has an option to control this situation.

To protect the beneficiaries, there are provisions to prohibit the State from using this option, if there was a surviving spouse, or a minor child.

And these are the kinds of prohibitions that are clearly needed.

GENERAL MEDICAID SAVINGS AND BUDGET ESTIMATES

Senator WEICKER. The only thing I question in the sense of my job is the projected savings—to me a rather large amount of money is being put out here.

Just out of curiosity, if these things don't come to pass, what are you going to do, and there are not a whole lot of projected savings in here.

Dr. DAVIS. Obviously, we receive quarterly reports from the States with updated estimates and if we need more money we would have to come back for a supplemental.

But in general we had very good success with our actuaries and their projections.

Mr. ITTEILAG. Senator, in the medicaid account also the appropriations request does include language which when we run short, if we would have run short in a particular fiscal year, we can borrow against the succeeding years' appropriation.

So it would not engender a crisis in the middle of fiscal year with respect to the Federal Government's ability to provide to the States on a timely basis the amount of medicaid money that they would deserve under the law.

I think part of this is the way we have a formulating budget; it's not unlike the way we formulate all of the budgets in the Department. In other words, we try to make an honest estimate of these savings, given the factors that we know at that time. To the extent we do that, I think it provides additional flexibility in the rest of the budget.

Clearly, if we projected no savings or very little savings it puts pressure on other parts of the budget.

Senator WEICKER. No; first of all let me say this: I don't care how you hack it, whether you can borrow against next year's appropriations or borrow it somewhere else, the fact is that ultimately, the funds are going to have to be provided by the Congress.

Mr. ITTEILAG. That's correct.

Senator WEICKER. Even though philosophically insofar as the human condition is concerned, I would probably be considered a liberal, when it comes to my fiscal practices, I'm very, very conservative, and that's why I am having problems with the budgets that are being presented to me by the administration.

I'm having problems on the one hand of legislation on the appropriations bill—we've already gone through that—and second, the administration in effect is patting itself on the back before anything has been proven out.

They're saying that the laws which we enacted 1 year ago are going to save *x* number of dollars. We don't have the proof in hand, they're saying, but this is what we expect.

I think you as a budget officer know just as well as I do that in the norm during the course of the budgetary process, the fiscal conservative takes the worst-case scenario, if he doesn't have any actual experience at nand, and we're not taking the worst-case scenario at all in any of this.

It's the administration saying that this is what we're going to save by virtue of what we enacted into the law and what we expect to go ahead and enact in the law in other instances.

Dr. DAVIS. Senator, in the case of the medicaid estimates, we find that the November estimates that the States give us generally are within 2 percent of what the totals will be. Historically they've been pretty good.

Senator WEICKER. Well, again, you'll have your chance. In the course of next year's hearings, if you're proven out to be right, I can assure you that I hope I have the graciousness to so indicate publicly.

1983 SOCIAL SECURITY AMENDMENTS

On the other hand [laughter] the recent social security legislation approved by Congress made a number of changes in medicare, changes which would alter your fiscal year 1984 budget requirements under the subcommittee's jurisdiction.

We're aware that the Government will have to contribute more than planned in January for its share of the part B insurance under medicare.

What are the changes and what are the additional funding requirements?

Mr. FISCHER. Senator, under part B, the changes that were enacted will require a net increase of $379 million in the request that's before you for the payment to the health care trust funds.

That consists of two changes. First, as a result of the delay of the increase in the part B premium and the change to calendar year financing, we will require an additional $519 million for the Federal payment to the supplementary medical insurance trust fund.

That is offset partially by a decrease in our payment for military service credits due to changes in the nature of this activity resulting from the Social Security Amendments of 1983.

So that's why the net increase, and that is $379 million.

MEDICAL LIBRARIES

Senator WEICKER. Your justifications talk about simplifying or eliminating excessive regulation. One of your regulatory proposals, as we understand it, would drop the requirements that hospitals have medical libraries as a condition of participating in medicare.

Why is that a particularly good move?

Dr. DAVIS. When we proposed that change, we were simply saying that a library is not required by statute. It does not mean that we would stop paying for the costs of medical libararies. It simply means that we would not have a reference in the regulation that would tell a hospital that it had to have a library and how it should be set up and run.

But again, I'd like to stress that if a hospital has a library, those costs would be recognized. Also this is only a proposed change.

Senator WEICKER. Apparently, the comment is made to staff by your agency that the requirement for medical library does not directly relate to health and safety issues.

Do you agree with that?

Dr. DAVIS. I think in the context of health and safety, meaning the health and safety inspection regulations, that is true.

One can also take a different interpretation and say that if a hospital has an up-to-date library where journals are available that keep the staff fully informed of the latest medical developments, that that would improve health and safety.

But you can't mandate that the staff use the facility to acquire the knowledge, nor can you mandate that they keep their libraries up to date.

I myself have visited a number of very small hospitals, 25 to 35 bed hospitals, and have seen their libraries—judging from the quality of these libraries I wouldn't say they made a significant contribution to health and safety, but again I think that's up to the individual hospital's judgment.

What we're simply saying is that we wouldn't require it, but that if it were there, we will pay for it.

MEDICAID ERROR RATES

Senator WEICKER. Last year's tax law established a 3-percent target error rate for medicaid beginning just a few days ago, and does the Department intend to apply the fiscal sanctions authorized in the new law to States failing to reduce their medicaid error rates to 3 percent?

How's that going to be done?

Dr. DAVIS. Under the new law, that is to be done in a prospectively determined fashion, and our estimate for 1983 is $12 million. There are approximately 10 States that would probably be liable.

Mr. SCOTT. The statute provides that the final number of States will not be determined until corrective action plans are reviewed. The number of States may vary.

But we do want to be sensitive to the fact that since the data is old and so many States are doing a good job of trying to correct their situation, we think that those good faith efforts ought to be rewarded.

Dr. DAVIS. Then, I think it is important that the States have reduced their error rate significantly. The overall error rate now is running 3.8 percent, which is significant, down from several years ago when the error rate was 6.8 percent——

So they clearly are working in this fashion.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. Thank you very much. There are further questions which I would appreciate responses to for the record.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

Questions Submitted by the Subcommittee

MEDICAID BUDGET REQUEST

Question: The Subcommittee is interested in what assumptions went into building your fiscal year (FY) 1984 Medicaid request. We want to focus on existing law. In FY 1983, your appropriation was $19.3 billion, but in FY 1984, your comparable budget request is a little over $21 billion. How do you reach that number? What drives it? Hospital rate increases?

Answer: Estimates submitted by the States in November 1982 are the basis for the FY 1984 budget request. Health Care Financing Administration (HCFA) has adjusted the State estimates for the anticipated impact of legislation which was not considered in the November 1982 State submittals (e.g., cost savings from Omnibus Reconciliation Act of 1981, Section 2161, and the Tax Equity and Fiscal Responsibility Act (TEFRA).

The States' FY 1984 projections are $1.9 billion over FY 1983. Price changes are providing the major impetus to increasing costs. Sixty-four percent of all States (73 percent of the top 15 States) expect double-digit inflation to continue in inpatient hospitals (10.3 percent). However, the magnitude of rate increases in inpatient hospitals is declining when compared to estimated 1982-1983 growth (14.8 percent), as States initiate cost savings measures in an attempt to curb spiraling costs.

MEDICAID BASE

Question: We note that as part of your request you are assuming savings of some $400 million as the result of recent changes in law, such as allowing the States to impose copayments for care and to put liens on the property of those confined to nursing homes. You also hope to recoup savings under some new policy directives. To what extent are your assumed savings optimistic?

Answer: The savings of $400 million is based on saving $275 million from implementing the recent changes in TEFRA such as optional copayments and liens; $90 million from increased third party payments collected through the Office of Child Support; and, $35 million from the implementation of the Family Responsibility issuance.

The savings estimates have all been developed by our actuaries in consultation with program specialists. The degree to which the estimates are optimistic or pessimistic depends on the accuracy of our assumptions. The primary assumption which HCFA has no control over is the degree to which States implement the optional changes. For the most part, all of these changes are optional for the States. If more States or fewer States implement a given policy, our estimates will be off to that degree.

Question: Let's take one example. You apparently hope to recover about $89.5 million from the health insurance of absent fathers who are under court orders to pay child support. This is a new program. Do you expect it will begin producing results immediately -- and to the full extent you hope?

Answer: The target effective date for this new program is October 1, 1983. The regulation relating to this will be published this Spring. This will give the States adequate lead time to have operating programs in place. They already have a program in place to collect child support from absent parents, so this effort is already an expansion of an existing program.

Question: Another example: you hope to recapture net savings of $35 million from getting adult children to contribute to the nursing home support of their indigent parents. This is based, we gather, on the States passing legislation to implement the concept -- legislation that could be controversial. Again, isn't there more optimism than justified that you'll get the savings?

Answer: The savings estimate was developed assuming that States representing 50 percent of the expenditures would develop such a program. A number of States are actively debating this subject. Idaho has just recently passed such a law. Virginia and Indiana have such laws on their books, but have not developed implementing regulations. Other States are currently debating various bills in their State legislative bodies. This estimate is extremely sensitive to State implementation action.

Question: If these savings don't materialize, what do we do then? How much more will we have to appropriate beyond the $21 billion?

(Note: On the issue of adult children contributing to parental support in nursing homes, the agency put out its interpretation in the Medicaid manual. No legislation or rule-making was involved. Also see next question.)

Answer: It is unlikely that all of the $400 million in savings would not materialize. However, if this total amount did not materialize, we would either request a supplemental or borrow from the FY 1985 appropriation.

FAMILY RESPONSIBILITY SAVINGS

Question: In your budget submission for Medicaid, you project savings of $35 million under "Family Responsibility for Long-Term Care Patients." The apparent idea here is to hold adult children financially responsibilie for indigent parents residing in nursing homes, but you provide very little information. What law or regulation are you using to implement these savings -- and what guidance have you given the States on implementation?

Answer: The recent clarifying instruction to the States was based on our General Counsel's interpretation of Section 1902(a)(17) of the Social Security Act, that, in essence, told States that their laws of general applicability did not conflict with the limitations set out in the Medicaid statute. The guidance we have provided States is the instruction, which was released in February 1983.

Question: How much would an adult child have to contribute to a parent's nursing home costs under your approach? Ten percent of costs, 50 percent, or more?

Answer: Determination of appropriate levels of contributions is a matter that is entirely within the purview of the State.

Question: What sort of financial disclosure, if any, would be required of families under your proposal?

Answer: Under our General Counsel's interpretation, the State determines the extent of financial disclosure, as it sees fit.

Question: To what extent could you, or a State, attach a child's income, home and other assets to offset Medicaid costs of nursing home care for an indigent parent?

Answer: Again, this would be a matter for the State to determine. I wish to underscore that this policy merely reflects an interpretation that any monies actually received pursuant to a State's generally applicable support statute is income to the recipients of the Medicaid long-term care. In this regard, how the State chooses to administer any support program is their perogative.

Question: Your budget shows you spending $81 million on this effort in FY 1984. How will this money be used? Where are the savings?

Answer: The Medicaid budget assumes in FY 1984 that $116 million will be saved in benefits and that there will be cost of $81 million from the Family Responsibility proposal. The $81 million for administrative expenses assumes that the States which establish such a program will need to set up an organization similar to the one that the Office of Child Support uses to collect child support payments from absent parents. To the extent that States use existing resources already in place, these costs would be reduced.

MANDATORY COPAYMENTS

Question: The Administration is proposing legislation to shift from optional to mandatory copayments for Medicaid beneficiaries seeking nonemergency care. These would be nominal copayments in the range of $1.00 to $2.00. Since the provision for "optional" copayments was started with the current fiscal year, why don't you try to get more experience with it before seeking a mandatory requirement?

Answer: It is the Administration's belief that an optional copayment system does not go far enough. All recipients of health care must share in the costs of their care in order to be motivated to reduce inappropriate utilization. Without mandatory participation of all States, the added impact of recipients reducing their own utilization will be lost on the total package of competitive health care reforms. Given skyrocketing health care costs, we must act now.

Question: You claim that mandatory copayments will save $249 million in fiscal 1984, but last year you estimated that such a requirement would produce $370 million in savings in FY 1984. Why the difference?

Answer: The first year savings from last year's proposal were $329 million which is $80 million more than the first year savings of the new proposal. The primary differences are: (1) approximately $50 million in savings is already assumed to have been achieved by the States in the service categories which were made optional under Tax Equity and Fiscal Responsibility Act (TEFRA) and (2) the remaining difference in the two estimates represents the use of additional data on the percentage of categorical versus non-categorical recipients.

Question: To what extent will any of your projected savings accrue because beneficiaries will not use Medicaid in order to avoid the copayments?

(Note: The agency says $36 million in savings is due to "deferred utilization".)

Answer: The estimate for the mandatory copayment assumed for the $249 million saved in FY 1984 that $100 million will be from the offsetting collection of the copayments and $149 million will be from the reduced utilization of inappropriate services. The TEFRA optional copayment proposal is expected to save $90 million in FY 1984 of which $54 million was assumed to be from the offsetting collection of the copayments and $36 million was attributed to reduced utilization.

ASSIGNMENT OF RIGHTS

Question: You are proposing changes which would require applicants for Medicaid to assign private health insurance rights to the State Medicaid agency. You estimate $6 million in savings in FY 1984. What evidence do you have that people who would be eligible for Medicaid have private or third party health insurance coverage?

Answer: A series of Medicaid third party liability studies has indicated potential additional savings of at least $200 million annually through full maximization of third party recoupment. This proposal would facilitate the recoupment of third party funds in that the assignment of rights overcomes the necessity to obtain subrogation on individual claims.

Question: To what extent do your projected savings of $6 million from this proposal amount to scraping the bottom of the barrel in pursuit of a very small return?

(Note: The proposal would increase the State's ability to obtain information on private health insurance among those applying for Medicaid.)

Answer: The mandating of the assignment of rights is one step in a series to recover the untapped resources of Medicaid recipients through third party liability. As indicated previously, studies show the availability of at least $200 million annually in

additional third party resources for Medicaid. We are attempting to use all possible means, including the mandating of the assignment of rights, to work toward achieving more of these potential savings.

HELPING THE MENTALLY RETARDED

Question: The Reconciliation Act of 1981 allows the Secretary of HHS to grant waivers to the States to allow them to provide home care for the mentally retarded and thus avoid putting them in institutions. What sorts of services are provided and how many States have taken advantage of this procedure?

Answer: The Secretary as of March 31, 1983 has approved a total of 22 Home and Community-Based (HCB) waivers directed to the mentally retarded, requested by 20 States. Eight additional waiver proposals are pending. Services provided under these waivers have varied widely; some have limited services to habilitation alone. Others have included all services listed in the 1981 statute, i.e., case management, homemaker, home health aide, personal care, adult day health, habilitation and respite care. Most waivers have also included one or more additional services such as: Transportation, nursing, early intervention services, family involvement services, durable medical equipment, occupational therapy, physical therapy, speech pathology, minor home/community residential adoptions and psychological services.

Question: How is this program coordinated with the Developmental Disabilities Act, both at the Federal and State levels, to make certain the best, most effective care is provided?

Answer: Because each State Medicaid plan and HCB waiver is unique, the major thrust of coordination takes place at the State level. Health Care Financing Administration does enforce statutory and regulatory requirements that States establish formal interagency agreements to assure the coordination of Medicaid services with other services provided through State health and rehabilitation programs.

One aspect of Federal coordination efforts has been HCFA's participation in monthly meetings of DHHS' Board and Care Coordinating Unit. This unit was established by former Secretary Schweiker to coordinate Departmental efforts to improve implementation of the Keys Amendment. This coordinated enforcement effort is also reflected in HCFA's draft final regulations governing approval of State proposals to provide home and community-based services under Secretarial waiver. When published, these regulations will provide that HCFA will not approve a HCB waiver unless the State has assured us that facilities covered by Keys Amendment standards in which HCB services are provided are in compliance with applicable standards under Section 1616(e) of the Social Security Act. In addition, services in facilities which do not meet health and safety standards, including Keys standards, would be ineligibile for Federal matching payments.

Question: We also understand there is a section of last year's Tax Act (Section 134) that permits States to provide Medicaid to certain disabled children living with their families. How does this fit into the picture?

Answer: The provisions of Section 134 permit States, at their discretion, to cover under Medicaid certain disabled children, at age 18 or under, who are living at home. A State can extend such protection to an individual who would be eligible for SSI, and therefore Medicaid, if the person were in a medical institution. In order to qualify under this provision, the child must also: 1) require the level of care provided in an institution, 2) be able to receive such care appropriately outside of the institution, and 3) be able to receive such care in the home at less cost to the Medicaid program than the cost of the institutional care.

The Department has established a broad range of options available to States in order to address the issue of home versus institutional care. In response to the plight of the Beckett family in Iowa, the Secretary promptly established a procedure for States to submit individual cases where consideration of parental income was the sole impediment to Medicaid eligibility for care in the home. Under this procedure, the Secretary can waive the need to consider parental income pursuant to a waiver authority in the law. A number of such requests have been received thus far and most have been approved, allowing these individuals to receive Medicaid payment for care in the home when it appeared that institutional care was the only possible alternative. The Department also permits States that apply for a waiver to provide home and community-based services under the provisions of Section 1915(c) of the Act to not consider the parent's income in establishing a child's eligibility for home and community-based services. This option has also been included in the model home and community-based waiver, which is a smaller scale version of the home and community-based waiver that is more readily processed by the State. Under both waivers, States can identify particular populations to receive services and can tailor covered services to address the special needs of the population covered under the waiver.

As the above description illustrates, States have the option of requesting consideration of such cases on an individual basis, of including such cases under the provisions of their home and community-based waivers, or exercising the option under Section 134 of a statewide waiver of consideration of parental income in such cases.

LIEN AGAINST PROPERTY

Question: The Tax Act of 1982 provides States with new authority to impose liens on the homes and other property of Medicaid patients who are likely to be confined to nursing homes for the remainder of their lives. You are projecting savings of $60 million in FY 1983 and $127 million in FY 1984. What experience have you had with this program that gives you confidence you will achieve the savings you have indicated?

Answer: Prior to the passage of Tax Equity and Fiscal Responsibility Act (TEFRA), Title XIX precluded States from imposing liens on the property of Medicaid recipients except under

extremely limited circumstances. As a result, our actual experience with a liens program is quite limited. However, our estimate of the potential savings as a result of States being allowed to impose liens and make adjustments and recoveries within the framework of the liens provision is based on the best information available concerning the number of Medicaid recipients who could be expected to be subject to having a lien imposed on their property and the potential value of the property in question. These projections show that the potential savings are as indicated.

Question: The law requires that those against whom liens will be placed will get a notice and opportunity for a hearing. You're not suggesting that the elderly and infirm are going to be hauled out of nursing homes to attend hearings, are you?

Answer: The liens legislation provides that the States will establish the procedures under which notices are given and hearings are conducted. The manner in which hearings are held is therefore within the purview of the States and outside the jurisdiction of the Federal Government. However, we would assume that States will recognize the physical limitations of the elderly and infirm in nursing homes and establish procedures for conducting hearings that take those limitations into account.

Question: There's an implication here that the States or the Federal Government may wind up owning a lot of houses and other property after the liens are closed. What can you tell us about this -- and how will property values be affected by the liens?

(Note: Under the law, liens are prohibited if the nursing home resident's spouse, minor or disabled child lives in his or her home.)

Answer: Because the imposition of and foreclosing on a lien are actions taken by the State, rather than the Federal Government, the Federal Government will not acquire any properties as a result of the liens provision. Whether and to what extent States find themselves with houses or other property as a result of foreclosing on liens will depend on the procedures each State establishes for making such foreclosures. The effect of the liens provision on property values is, of course, difficult to determine. The number of houses against which liens are imposed will be a very small percentage of the total number of houses on the market at any one time, so the effect on property values in general would be negligible. However, the value of an individual house on which a lien was imposed could be adversely affected, although in all probability to a very limited extent. Any lowering of the value of such a house would probably result from the slight additional legal complication of dealing with the lien when the property is offered for sale.

NEW NEEDS

Question: The recent Social Security legislation approved by Congress also made a number of changes in Medicare -- changes which would alter your FY 1984 budget requirements under this Subcommittee's jurisdiction. We are aware that the government will have to contribute more than planned in January for its share of the Part B "doctor bill" insurance under Medicare. What are the changes -- and what are the additional funding requirements?

Answer: As a result of the Social Security Amendments of 1983, the Federal contribution for Part B will be higher than anticipated. This is due to the fact that the adequate rate which, prior to the Amendments would have increased in July 1984, will now increase in January 1984 and also because the premium increase scheduled for July 1983 will not take place until January 1984 with the Federal contribution making up the difference between the "frozen" premium and the premium that would have been in place. Our preliminary estimate is that we will require an additional $519 million for this activity.

FY 1984 RESEARCH AMENDMENT

Question: We understand the Medicare legislation mandated quite a number of studies, many related to the new fixed-price system based on "diagnostic-related groups." How many of these studies will have to be funded through the appropriations we provide - and how much money are we talking about?

Answer: Our FY 1984 budget estimate of $30 million for HCFA research does not include funds for the studies included in the 1983 Social Security Amendments. Since the majority of these studies require reports in 1984 or 1985, it is essential that we initiate these studies immediately. We are currently examining our funding needs for these requirements and will advise you of any changes which need to be made to our FY 1984 budget request.

PART B COSTS

Question: The Subcommittee is concerned as to whether you have requested a realistic amount of money for Part B of Medicare --Supplementary Medical Insurance (SMI). Your budget request is $16.2 billion --an increase of $2 billion over FY 1983. Your justifications indicate you are making a "current law" request for SMI. But it appears that this number does not take into account Congress' action in delaying the premium increase in Part B from this July 1st until next January 1st to coincide with the new date for Social Security cost of living adjustments. How much will this change add to the $16.2 billion you are requesting for Part B?

(Note: The agency has told us that its actual need may be $100 million to $655 million more than the budget asks--depending on what legislative proposals, including savings, are approved by Congress.)

Answer: The budget request was prepared before Congress' action on the Social Security Amendments of 1983 and therefore could not have taken their impact into account. Our preliminary estimates are that our request for this activity will increase from $16,292 million to $16,811 million or by $519 million. When this estimate is finalized we will send a budget amendment to the Committee.

MEDICARE CHANGES

Question: Congress has agreed to sweeping changes in Medicare reimbursement. We will move in a series of stages from a cost-based system to Prospective Reimbursement which is based on diagnosis of a patient's illness. There has been some apprehension

expressed that hospitals may seek to increase their reimbursement under the new system by increasing admissions and readmissions and upgrading diagnoses to more expensive categories. What steps, including utilization review, will you take to protect the new system from such possible abuses which could increase Medicare costs?

Answer: Our Admission Pattern Monitoring (APM) plan will identify increases in admissions based upon Medicare billing data, and the medical review agent will determine if the increase is inappropriate. When the medical review agent detects a problem, remedial action will be taken. Actions taken will range from educational efforts to monetary penalties and sanctions for more egregious offenses.

Health Care Financing Administration also plans for medical review agents to perform diagnostic-related group (DRG) validations. On-site review of the medical records will be performed to ascertain that the diagnosis used to arrive at the DRG is confirmed by the medical records. Reimbursement amounts will be revised if errors are found. If a pattern is detected, there will be intensified review of certain DRGs for an individual physician, or of all cases from a particular provider.

Repeat admissions, which result from premature provider-instigated discharges, will be handled also by the quality review system.

PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS/ PEER REVIEW ORGANIZATIONS

Question: It appears that the new Medicare legislation thwarts your efforts to kill Peer Review Organizations (PROs). Now, hospitals receiving payments under prospective reimbursement will be required to contract with PROs to review diagnostic information supplied by such hospitals. Are you ready now to give life to the new PROs?

Answer: We intend to implement the law. The new prospective payment legislation effectively requires that the PROs be implemented no later than October 1, 1984. Tax Equity and Fiscal Responsibility Act (TEFRA), as modified by the Continuing Resolution for FY 1983, requires us to continue to support effective and efficient PSROs until such time as the PRO program is implemented.

MEDICAL LIBRARIES

Question: Your justification talks about simplifying or eliminating excessive regulation, which sounds good. Yet, one of your regulatory proposals, as we understand it, would drop the requirement that hospitals have medical libraries as a condition of participating in Medicare. Why would you not want hospitals to have medical libraries -- isn't that an important professional tool for the medical staff at such hospitals?

(Note: The agency has told us that "the requirement for a medical library does not directly relate to health and safety issues." This seems a rather narrow perspective.)

Answer: The Federal requirement that a hospital have a medical library is considered to be unnecessary. The question is not whether we want hospitals to have medical libraries, but whether the absence of a Medicare regulation will result in hospitals failing to keep current information. There is no indication that hospitals will not meet professional informational needs without Medicare surveillance. We believe that hospitals responsibly meet such needs already. We do not find deficiencies in this area. Further, continuing education already accomplishes much of the intent of the standard without regulation. Continuing medical education allows professional staff to receive information specific to their interests and needs. Other changes in new information retrieval technology, as well as cooperative arrangements among libraries and between institutions, have diminished the need for libraries in all hospitals.

In any case, medical libraries will continue to be reimbursed as an allowable cost under Medicare. Finally, the mere existence of a hospital medical library does not guarantee its use by staff. Hospitals that see a need for a library will continue to maintain one and Medicare will continue to pay its share of such costs.

Question: To what extent is your proposal to eliminate the medical library requirement inconsistent with the requirement for hospitals' accreditation by the Joint Commission on Accreditation of Hospitals (JCAH)?

Answer: The Joint Commission on Accreditation of Hospitals (JCAH) requires a professional library service. This requirement may be met through cooperative arrangements with other professional libraries and/or information systems. Each hospital need not maintain an inhouse library.

MEDICAID ERROR RATES

Question: Last year's tax law established a three percent target error rate for Medicaid beginning just a few days ago -- March 30. Does the Department intend to apply the fiscal sanctions authorized in the new law to States failing to reduce their Medicaid error rates to three (3) percent? How will it be done?

Answer: Once the error rates for a given period are finally determined, adjustments will be made to States' Federal matching monies. Since the Department will prospectively withhold money from any State for which it projects an error rate in excess of three (3) percent, adjustments should be minimal. Before the beginning of each quarter HCFA will project an anticipated payment error rate for each State for that quarter and reduce that State's award for Federal matching for that quarter by the percentage by which the anticipated payment error rate exceeds the 3-percent national standard. Projections will be based on error rate data for the two most recent 6 month periods available. A disallowance-liable State, may, at the time of final disallowance, request waiver of the penalty; it may not, however, request waiver of amounts to be prospectively withheld.

Question: How many States do you believe will be penalized? How many "corrective action" plans will you accept in place of assessing penalties?

Answer: Sixteen States have been projected to be penalty-liable for the first TEFRA period. Current corrective action efforts were considered in determining the amount of the projected error rate. It is, of course, impossible to determine at this point in time how many of these sixteen States or other States, will actually be liable and will devise plans that will actually lower error rates. It is obviously in a State's interest to prepare and perform an effective corrective action program, not only because a disallowance may then be waived, but also to avoid misspending its own scarce resources.

Question: What assistance is the Department providing to the States to help them to reduce their Medicaid payment error rates?

Answer: The primary purpose of Federal quality control is to provide management information to States to assist them in targeting their corrective action plans. Inherent in the quality control process are also requriements for the analysis of the incidence and cause of eligibility errors. States have therefore designed and implemented, with Federal advice, error analysis systems and protocols for interpreting results for the purpose of corrective action planning. The Department provides advice on designing such systems and protocols, and critiques proposed corrective action plans. In addition, the Integrated Quality Control System, which combines quality control systems for the Medicaid, Aid to Families with Dependent Children (AFDC), and Food Stamp programs, should provide additional information and enhance the capability of States to determine the cause of errors.

Question: To what extent is there substantial variance among the States in Medicaid payment error?

Answer: The variance is not great. The highest projected error rate for the April 1, 1983 quarter is only 7.7%. As corrective action plans become more and more effective, the variance should be even less.

QUALITY OF CARE

Question: Congress, as you know, has temporarily blocked the Department's efforts to eliminate the requirement for annual inspections of nursing homes. Such inspections are needed to assure that Medicaid beneficiaries receive acceptable care. Why shouldn't Congress continue the present moratorium to assure that even the good nursing homes don't backslide on the quality of care?

Answer: Although we are currently surveying all nursing homes on an annual basis, we continue to believe the best approach is to target on poor performers and to survey good facilities less frequently. However, HCFA will consult with Congress and all other interested and affected parties in the review of the proposed revisions to the Survey and Certification process.

FY 1984 RESEARCH AMENDMENT

Question: The Committee has been most pleased with the extent to which the HCFA Office of Research and Demonstrations has been responsive to its interest in exploring the relationship between physical health costs and the delivery of mental health services, as well as the cost-effectiveness of utilizing geriatric nurse practitioners. The Committee is concerned, however, with the number of studies that have recently been "mandated" by the Congress; for example, under the provisions of the Social Security Act Amendments of 1983. Accordingly, the Committee would appreciate learning how HCFA feels that it will be able to respond to these requests, and others that this Committee may make, within its budgetary limitations.

Answer: The $30 million proposed in the FY 1984 budget includes funds for previously mandated projects or reports (such as the Tax Equity and Fiscal Responsibility Act of 1982.) We are carefully reviewing our research agenda to accommodate the most important mandated projects first and to be as responsive as possible to reporting dates.

Question: We're concerned about your various ideas for loading more Medicare costs on the elderly who already pay a substantial share of the bill under the program. For example, you've been talking about raising the premium under Part B "doctor bill" insurance from the present 25% to 35% by by 1988. We estimate this would push up the annual premium from $146.40 to $370.80 -- a difference of $244. How can you justify this?

(Note: For Calendar Year (CY) 1981 it's been estimated that 42.3% of expenditures for physician services for the elderly came from private sources. Medicare accounted for 54.5% and the rest came from Medicaid and charity.)

Answer: Initially, in 1965, the premium on Medicare Part B was set at 50% of program expenses. Beginning with the premium that went into effect July 1, 1973, Congress mandated that the annual increase in the premium could not exceed the prior year's Social Security benefit increase. As a result, the share of program costs covered by the premium fell rapidly until it reached a low of 24% in 1981. This drop was halted by the TEFRA legislation, which established a minimum limit of 25% of program costs. Our proposal is intended to achieve a more equitable balance between general revenue and premium financing of Medicare Part B, and to move toward bringing the beneficiaries' share of program costs more in line with the original design of the program.

Question: You've also been pushing the idea of skipping a year in amending the "fee screen" which is used to update physician charges reimbursable under Medicare. To what extent would this approach impel doctors to refuse to accept 1983 -level payment in 1984 -- or load additional charges on their Medicare patients to make up the perceived difference?

Answer: We hope physicians will accept this proposal in the spirit in which it is offered. Everyone, including physicians, must do their part to reduce the Federal deficit and keep inflation

down. However, even if physicians choose to ignore our appeal and do raise their fees, the impact on individual beneficiaries will be relatively small.

In some instances, physicians may refuse to accept assignment. The assignment rate may decrease, and out-of-pocket costs for Medicare beneficiaries may increase. However, two factors may mitigate against any assignment rate decline. As private payors and State Medicaid programs increase their cost containment efforts, Medicare rates will still be competitive. Moreover, with the large increases in the number of new physicians, competitive market forces should mitigate against a significant decline in the assignment rate.

SECOND OPINIONS

Question: We are aware that the Inspector General (IG) of HHS has said that the government could save more than $150 million if Medicaid and Medicare patients were required to get a second opinion before agreeing to elective surgery. We know that the government encourages second opinions, but is it true that you do not favor a mandatory program until more studies are conducted?

Answer: In a response to the draft IG report, HCFA indicated that there are a number of operational issues that remain to be answered before a national program could be implemented. In addition, HCFA is withholding judgement about the IG findings until we are able to evaluate the results of our own research study scheduled to be issued in October, 1983.

Question: Haven't several states (Massachusetts, Michigan and Wisconsin) adopted mandatory second-opinion programs with some success in operations avoided and money saved?

Answer: Yes, it is our understanding that all three states have implemented mandatory second surgical opinion programs for Medicaid beneficiaries. HCFA is evaluating the Massachusetts program. Preliminary findings indicate that 1,600 surgeries were foregone annually:

- 1,100 were for tonsils/adenoids; and
- 130-140 each were for hysterectomies, gall bladders, submucous resections.

Net program savings are estimated to be $1 million. However, some concerns still remain such as the applicability of these results to the Medicare population, the administrative costs involved, and possible negative health outcomes due to delayed surgery.

Question: Some experts apparently believe that second-opinion programs might have the effect of convincing people they need to undergo an operation and result in an increase in the surgery rate. What's your view?

Answer: HCFA's second opinion surgical evaluation is addressing this issue. Preliminary results indicate that the net increase due to confirming second opinions is likely to be negligible. Final conclusions of the study will be available on October, 1983.

MEDICARE CONTRACTOR COMPETITION

Question: Normally, Medicare Contractors are selected without competition, but it's been argued that you might get more for your dollar by having the private sector compete for the job of Medicare claims processing and payment. What are you doing in the area of competition? And what experience have you had with it?

Answer: Health Care Financing Administration currently has five fixed priced competitive claims processing and payment contracts. These are Part A in New York and Missouri, Part B in Maine and Illinois, and Part A and B in Colorado. In general, the results achieved by HCFA under the experimental contracts have been positive. Problems were experienced under the Illinois experimental Part B contract, but the contractor has made significant strides toward rectifying them.

Health Care Financing Administration has reached a number of conclusions through these experimental contracts. Competitive contracting has been found to be a viable alternative to current contracting methodology. Prospective contractors have displayed a substantial interest in engaging in the competitive process. Competitive contracting has reduced the administrative costs of operating the Medicare program. These cost reductions can be accomplished without degradation, and often with improvements, in service to both beneficiaries and providers. In addition, competitive contracting, especially contracts with positive and negative incentives, produces innovations and operational methodologies that were heretofore not seen in cost reimbursement contracts. This has provided an inducement for existing cost reimbursement contractors to improve the quality of their operations while attempting to reduce administrative costs. HCFA has learned to effectuate a transition from an incumbent to a new contractor with minimal disruption in service to beneficiaries and providers. Competitive contracting has been shown to produce positive results in terms of cost savings as well as quality of service.

Consequently, our FY 1984 budget includes a legislative proposal to increase the Secretary's flexibility in the area of competitive contracting.

COMPETITIVE FIXED-PRICE CONTRACTING

Question: In a recent review of the President's budget, General Accounting Office (GAO) said of your experiments with competitive fixed-price contracting: "In two of the three experiments contractor performance and beneficiary and provider

services deteriorated during and after contractor change over, and program payments were not adequately controlled." What are your comments on this? And to what degree were the problems a function of the lack of a skilled workforce?

(Note: It appears the agency plans to allocate $41 million to fixed price contracts in FY 1984.)

Answer: The GAO report "Experiments Have Not Demonstrated Success of Competitive Fixed-Price Contracting in Medicare" refers to the first three experiments conducted by HCFA. These were for fixed-price carriers to provide Part B services in the following States during the periods indicated:

Maine	7/1/77 - 9/30/81
Western New York	11/1/78 - 9/30/82
Illinois	4/1/79 - 9/30/83

A major indicator of the overall quality of a carrier's claims processing operation is the payment/deductible error rates generated by HCFA's statistically valid quality control review program. It has been HCFA's experience that any workload transfer, whether to a fixed-price or a cost contractor, generally tends to cause a temporary increase in these error rates during the implementation period. Such aberrations are not experienced solely under fixed-price experimental contracts.

In Maine, the fixed price carrier's payment/deductible error rate was back to pretransfer levels within a year (having risen above the national average performance level by only 0.3 of a percentage point for one quarter). For the remaining 3 years of its contract, the Maine fixed-price carrier operated satisfactorily, either at or below the national average payment/deductible error rate. In addition, the satisfactory level of beneficiary and provider services of the previous contractor was continued by the fixed price carrier during the entire term of the contract.

In Western New York, three carrier service areas were combined into one, increasing the complexity of transition activities. The payment/deductible error rate increased for one quarter by approximately one percentage point above the highest error rate exhibited by the three carriers prior to the changeover. The payment/deductible error rate for Western New York then declined rapidly. For the remainder of the 3 years that the fixed-price contractor operated in Western New York, payment/deductible error rates were below the national average. Overall, the accuracy of program payments improved for the service area as a result of the contractor changeover. Initially, the new carrier had problems with beneficiary and provider services, but showed marked improvement for the last 2 years of the contract.

Two carrier service areas were combined into one in Illinois. The payment/deductible error rate experience of the two pretransfer carriers had been higher than the national average since the inception of the quality control program in June 1976. The initial payment/deductible error rate of the new fixed-price contractor did increase four percentage points, but immediately

declined 0.8 of a percentage point per quarter on average over the next five quarters of operation. The carrier has shown even further improvements in program payment accuracy and is currently operating below the national average for payment errors.

Initial claims processing problems were due in large part to the contractor's location which was not able to provide a skilled workforce. This experience has led to a revision of the procurement process to more fully address the adequacy of the processing site, facilities, and workforce. Processing problems led to increased beneficiary concerns which exacerbated beneficiary service problems originally due to insufficient telephone service. The Illinois carrier, as indicated previously, has focused efforts on improving its claims processing operation and is still working with some success to overcome beneficiary service deficiencies.

CATASTROPHIC COVERAGE

Question: In proposing its Medicare cost-sharing legislation, the Administration apparently tried to sweeten the pot by also offering catastrophic health insurance coverage after a certian period of hospital confinement. When we examined the proposal, we found that the catastrophic plan would reach only about 150,000 of the 29 million Americans covered by Medicare. Why so few?

Answer: Although there will be 30 million Part A enrollees in FY 1984, only one quarter of those enrollees or 7.5 million will use hospital services during the year. In our proposal, no beneficiary would be required to pay either a deductible or coinsurance on more than 60 days of covered hospital care each calendar year. Approximately one percent of all stays are for 60 days or longer. When we adjust for multiple benefit periods during a year, we estimate that about 150,000 individuals would benefit from our proposal.

Question: Even with the new prospective reimbursement plan for Medicare, do you still see a role for catastrophic health insurance but covering a larger number of people?

Answer: Prospective payment for hospitals does not remove the need for catastrophic coverage, nor is there any particular reason that a larger number of people should be covered because of it.

MEDICARE CONTRACTOR BUDGET

Question: Congress has provided $820 million in FY 1983 for the activities of private organizations, mainly Blue Cross and Blue Shield, to handle claims processing and payment for Medicare. Will the FY 1983 appropriation be sufficient--and to what extent will you have to use the $20 million contingency fund that is part of your total allocation?

Answer: Our current budget projections show that the appropriation will be adequate. We do not anticipate that the contingency fund will be used unless unforeseen costs occur, such as increased workload or postage.

Question: Last year's Tax Act also gives you $45 million to finance more intensive work on audits and medical review. How have these funds improved your ability to do more work on audits and medical review--and will you have enough money for these purposes?

Answer: The additional funding has increased HCFA efforts in the area of audit and medical review. The funding has been allocated among contractors based on an analysis of data to assure that dollars are focused on areas of greatest potential impact. A monitoring system has been implemented to measure specific dollar savings. However, individual contractors have been given sufficient flexibility to design systems to accomplish specified goals in their service areas.

Question: As you know, audit and medical review return money to the government and may largely be self-financing. How do the numbers balance between costs and income for these activities?

Answer: We expect an excellent return for our investment in both audits and medical review. For each dollar spent on audits, we estimate a return of $5.70. In terms of medical review, we expect a return of $3.00 for Part A and $5.00 for Part B.

WELFARE ADMINISTRATION BLOCK GRANT

Question: The Administration's 1983 budget proposed a combined payment for the costs incurred by State and local welfare agencies in administering three programs -- Medicaid, Aid to Families with Dependent Children, and Food Stamps. This was proposed "welfare administration block grant" which Congress rejected. Where does the Administration now stand on the concept of a Combined Welfare Administration Block Grant?

Answer: The Combined Welfare Administration Block Grant which was part of the President's 1983 Budget request was rejected by Congress. We have not resubmitted this proposal as part of the 1984 President's budget.

Question: To what extent is the concept of a Combined Welfare Administration Block Grant consistent with Federal assumption of Medicaid costs under a "New Federalism" proposal?

Answer: The Administration has not proposed a Combined Welfare Administration Block Grant as part of the FY 1984 budget. In addition, the current version of the New Federalism initiative does not include the swap of responsibility for Medicaid and AFDC or Food Stamps since agreement could not be reached on all outstanding issues, particularly the nature and funding of the Federal Medicaid program.

HOSPITAL INFLATION

Question: One of the most stubborn components of inflation is rising hospital costs, particularly costs to the government for Medicare beneficiaries. While the growth rate in these costs is down from its highest levels, it still is projected to rise 13.5 percent from 1983 to 1984. What are the reasons for this continuing rise in the average daily reimbursement for Medicare hospital patients? How do you explain the 13.5 percent projected increase in light of the fact the the Consumer Price Index (CPI) itself is projected to rise only 4.7 percent during the same period (1983 to 1984)?

Answer: Over the past few years, hospitals costs have risen considerably faster than the medical care component of the CPI (see chart below).

The Medical CPI basically measures price changes for a fixed market basket of goods and services. The trend in average daily reimbursement for Medicare hospital patients measures not only price changes for a given set of goods and services but also changes in the mix of goods and services delivered. Changes in the technology of health care have lead to costlier types of health care products and services and increased specialization among providers. The aging of the U.S. population has made Medicare particularly vulnerable to these change.

All-Urban Consumer Price Indexes*			Medicare Inpatient Hospital Reimbursement Per Day
Year	Health Care	Hospital Room Confinement	
1982	11.6	15.7	16.3
1981	10.8	14.8	17.1
1980	10.9	13.1	13.3
1979	9.3	11.4	12.0
1978	8.4	11.0	12.2
1977	9.6	11.5	13.2

*Based on Data from the Bureau of Labor Statistics (U.S. Labor Department)

MEDICAID WAIVERS

Question: The Reconciliation Act of 1981 authorized the Secretary to waive certain requirements of Medicaid such as a beneficiary's freedom to choose a doctor or hospital. Waivers could give a State the right to direct the beneficiary to a lower cost provider avoiding, for example, expensive emergency room services. To what extent are States using waivers to re-direct beneficiaries to save money on Medicaid and can you estimate the savings?

Answer: To date, 13 States have had a total of 29 freedom of choice waiver requests approved. The individual requests vary in the number of beneficiaries they affect, ranging from several hundred to State-wide application. Currently, it is not possible to estimate the savings affect because the individual waiver projects have not been in effect long enough to yield reliable data on the extent of savings realized. This information will be collected as part of the State Assessment Process and through other studies.

Question: What have been the major changes in health care delivery patterns attributable to implementation of freedom-of-choice waivers?

Answer: While we expect significant changes in health care delivery patterns as the result of freedom-of-choice waivers, the various State projects already approved have not been in operation long enough (some of them haven't even started) to provide reliable indicators of the nature and extent of such changes. Most of the projects focus on services to small numbers and narrowly drawn categories of beneficiaries within a State. Therefore, even when fully operational, the major impact of the various projects will be seen primarily in the potential expansion of those projects to other areas of the State or to other segments of the State's recipient population.

Based on early indications, the primary care case-management mechanism (Section 1915(b)(1) of the Social Security Act) seems likely to represent the most important change in the way health care services are delivered. To date, some 20 case-management waiver projects have been approved, several of them involving Health Maintenance Organizations (HMOs) or Health Insurance Organizations (HIOs) which provide prepaid services on a risk-related, capitated basis. The primary care case-manager is responsible, either directly or indirectly, for providing primary care, and for overseeing the provision of all other Medicaid services on behalf of each recipient under his care. The recipient is no longer responsible for determining his medical needs and for choosing the appropriate health care services and providers to meet those needs.

The principal benefits expected through use of primary care case-management, all of which reflect on health care delivery patterns are:

1. Reduction in length of hospital stay.
2. Reduction in cost per admission.
3. Reduction in unnecessary utilization of services and facilities.
   (a) Reduction in use of hospital emergency rooms for non-emergency situations.
   (b) Curbing unnecessary doctor-shopping.
   (c) Curbing improper use of drugs.
   (d) Curbing laboratory and x-ray tests.
4. Reduction in inpatient hospital admissions.
5. Emphasis on preventive care.
6. Reduction in outpatient hospital use.
7. Provision of 24-hour, 7-day-a-week access to primary care physicians.

We have received no waiver proposals under section 1915(b)(2), which allows a locality to act as a central broker in assisting Medicaid eligibles to select among competing health care plans. We have approved only 2 requests under section 1915(b)(3), which allows sharing of cost savings through provision of additional services.

We have approved seven waivers under section 1915(b)(4), which allows restriction of providers, who otherwise meet all reimbursement, quality, and utilization standards under the State plan, to those who are most cost-effective and efficient. We anticipate that there will be cost savings and efficient provision of services under section 1915(b)(4) waivers, involving many of the same changes in health care patterns as those mentioned under section 1915(b)(1).

Question: What percentage of Medicaid recipients are expected to be affected by freedom-of-choice restrictions?

Answer: It is not possible, at this point, to predict the number or percentage of recipients to be affected by freedom-of-choice waivers. In some States, programs are implemented statewide; in others, programs are implemented in one or more counties, or sometimes for a specific population. Some programs permit voluntary enrollment, while others are mandatory. In addition, we have no way of predicting the number or scope of waiver requests that have not yet been received or the extent to which waiver projects already undertaken will be expanded to cover more categories or greater numbers of recipients.

Questions: What are the major problems which States and/or localities have encountered in administering Medicaid Freedom-of-Choice waivers?

Answer: Section 1903(m)(2)(A) of the Social Security Act prohibits Federal matching for payment determined under a prepaid capitation basis or any other risk basis for comprehensive services unless certain requirements are met. Comprehensive services are defined in paragraphs (2), (3), (4), (5), or (7) of Section 1905(a). If comprehensive services are to be provided on a capitated or prepayment basis, the seven requirements of 1903(m)(2)(A) must be met.

Many States have expressed interest in providing a package of services on a prepayment basis, particularly under a primary care case-management system 1915(b)(1) waiver. Typically the package of services the State wishes to provide through a case manager on a risk basis includes inpatient hospital, physician, laboratory and x-ray services as well as prescription drugs. When such a package of services is provided on a risk basis, the seven requirements of Section 1903(2)(A)(i), that the entity meet the definition of a health maintenance organization; 1903(m)(2)(ii), that less than 75 percent of the membership enrolled on a prepaid basis be Medicare or Medicaid recipients; and 1903(m)(2)(A)(vi), that requires voluntary disenrollment frequently present problems for implementation of the case management system.

Allowing States to waive Section 1903(m) requirements would facilitate implementation of freedom of choice waivers. When requesting these waivers, the State must already document the cost-effectivenes of the project and the effect on recipients regarding access to care and quality of services. This would not be lost if Section 1903(m) requirements were waived.

Section 1905(a) of the Act defines the groups eligible for medical assistance. Section 1915(b) does not authorize a waiver of that provision and in fact, limits case management systems to individuals otherwise "eligible for medical assistance under (title XIX)." Therefore, eligibility may not be extended to persons no longer meeting the statutory standards. States have indicated that a guaranteed eligibility period of up to 6 months is necessary in order to implement a cost effective and efficient case management system which is reimbursed on a risk basis. They argue that a guaranteed eligibility period is necessary to have a stable population.

MEDICAID INFORMATION SYSTEMS

Question: The Medicaid Managment Information System program is a computerized means of processing huge volumes of claims and verifying eligible recipients and providers. Under a 1980 law, the States had until last September 30 to get approved systems in business. Did all of the States make the September 30 deadline--or will some be faced with penalties, as the law provides?

Answer: All States except Maryland and Massachusetts made the September 30, 1982 deadline for receiving initial approval for an operational MMIS.

Massachusetts was granted a six month waiver for good cause. Subsequently, they have requested an additional one quarter extension due to circumstances beyond their control. This extension would last through June 1983. Maryland had been granted a six month waiver for good cause to March 31, 1983. We expect a certification decision on the Maryland MMIS to be available sometime in May.

Question: What is the status of the effort to put in performance standards for systems previously approved?

Answer: Medicaid Management Information System (MMIS) reapproval performance standards were developed to assess States' system operations. The Systems Performance Review (SPR) was first applied in 29 States with an approved MMIS during FY 1981. This application of SPR was a "dry run" undertaken to develop a data base and to assist States in improving their systems. During the FY 1981 review, 19 States failed the SPR.

Based on data from the FY 1981 review, the SPR was revised for FY 1982. This was the first year the SPR was fully operational. Thirty-two States were penalty liable if they failed to meet reapproval performance standards. The FY 1982 review resulted in the failure in at least one element in 11 States. Federal Financial Participation (FFP) penalties of from 5 to 9 percent of the 75 percent funding for an operational MMIS were imposed in 6 States. Five States were granted good cause waivers and were not subjected to the FFP penalty.

The six States facing an FFP reduction may have it restored. The reduction is temporary pending FY 1983 SPR results. If all parts of the FY 1983 SPR are passed, the Secretary <u>may</u> restore withheld monies.

Based on the experience of both FY 1981 and 1982, the SPR was revised for the FY 1983 review. Forty-one States are subject in FY 1983 to the SPR.

Question: What is the nature of the technical assistance you are providing to the States to assist them in operating Medicaid Management Information Systems (MMIS)?

(Note: We understand that 42 States and the District of Columbia have operational systems; 2 additional States expect approval in the current fiscal year.)

Answer: The primary Federal role in improving MMIS performance is through utilization of the Systems Performance Review. HCFA has revised the review to be more outcome oriented and to assist States in achieving acceptable performance levels. Federal assistance is provided to States on MMIS subsystems for Surveillance and Utilization Review, Long Term Care, Eligibility and Early Periodic Screening Diagnosis and Treatment. This is provided both on-site and by telephone.

RESEARCH SAVINGS

Question: Your fiscal year (FY) 1984 budget justification states that "projected Medicare and Medicaid costs in FY 1984 would have been at least $2 billion higher" were it not for the work carried out under research, demonstration and evaluation. What is the basis for this statement? Please cite examples of savings that you are referring to.

Answer: Actuarial assumptions for the budget include over $2 billion in program savings that resulted directly from Research and Demonstration (R&D). The major component of these estimated savings was the implementation of total cost limits, estimated to save $1,866 million in Medicare costs in FY 1984. Other program changes included in the $2 billion savings estimate were the elimination of the Medicare Private Room Differential, Elimination of the Nursing Differential, and revised methodology for Medicare and Medicaid payments for malpractice insurance. These latter three program reforms resulting from R&D were estimated to save $800 million in FY 1984.

END-STAGE RENAL DISEASE COORDINATING COUNCILS

Question: The purpose of the End Stage Renal Disease Networks is to promote high quality care for victims of End Stage Renal Disease. However, there has been criticism that Networks don't appear to be very successful in carrying out their mission, such as improving patient access to care. You request level funding for the program in FY 1984 ($4.5 million). What is your current view of the ESRD Networks?

Answer: We have proposed to abolish the ESRD Coordinating Councils, because the Councils have not been cost effective. Progress in achieving their objectives has been demonstrably slower than desired. The role which the Councils were expected to perform can be addressed more effectively through the design and implementation of reimbursement policies and procedures which will ensure appropriate incentives for economy.

MEDICARE

Question: The Administration proposed legislation to significantly increase cost-sharing for the average Medicare hospital patient.

Under the Administration proposal, the cost to the patient of the average 11 day stay in a hospital would grow from $350 to $530, with additional costs added as the length of stay climbs to 60 days. In an attempt to counter-balance these increases, the Administration would provide catastrophic coverage after 60 days of confinement, but it's estimated the catastrophic plan would reach only about 150,000 of the 29 million Americans covered by Medicare.

In light of the very small number of persons who would benefit from the proposed catastrophic coverage plan, how do you justify increasing costs to Medicare beneficiaries by some $710 million in fiscal year 1984 and billions more in the year ahead?

Answer: Although only 150,000 out of the 7.6 million beneficiaries who use Part A hospital benefits in a year will be helped financially by the proposed change, all beneficiaries will benefit from the knowledge that they are now protected against the risk of catastrophic hospital costs. Also the savings from the proposal will help to improve the financial position of the Hospital Insurance Trust Fund which, as you know, is projected to be depleted as early as 1988, under the most pessimistic assumptions in the 1983 Trustees Report, if no action is taken to reduce program expenditures.

Question: If your purpose is to reduce the cost of lengthy hospital stays, why not simply offer some catastrophic insurance to those beneficiaries who may want to buy it?

(Note: The Administration says that under its plan, a beneficiary requiring 150 continuous days of hospital care in FY 1984 would pay $1,530, compared to $13,475 in out-of-pocket costs without the plan. The Administration says the increased cost it proposes will "encourage cost-consciousness" among Medicare beneficiaries.)

Answer: The purpose of the proposal is both to provide catastrophic protection and to change the current financial incentives to encourage cost-conscious behavior among our beneficiaries and health care providers. To offer catastrophic insurance only to those beneficiaries who may want it runs counter to all principles of insurance and would leave the program open to significant financial loss due to adverse risk selection.

Questions Submitted by Senator William Proxmire

ESRD DATA COLLECTION

Question: Your agency apparently has been criticized for poor quality in data collection. What are you doing to improve data collection and using the Networks to help in the task?

Answer: HCFA is responsible for managing a comprehensive Departmental data base composed of a basic patient registry and a facility specific cost/treatment data base. Because Medicare supports the treatment of virtually all persons with chronic renal failure, HCFA has accumulated data on almost the entire ESRD population in the U.S. Thus, this Departmental data base has the potential of being the source of information on practices and outcomes associated with the treatment of ESRD.

In the past, we attempted to gather "all" information on "all" patients, but were not successful. We had problems with compliance, with gathering information which was not completed accurately, and with data elements which were not well defined.

To improve the quality of information, HCFA continually reviews its data collection mechanism. As part of this evaluation we have devised new forms, proposed a legislative sanction to ensure compliance with data reporting requirements, and enlisted the participation of the professional community in encouraging their colleagues to cooperate in the submission of complete and accurate information on their patients.

Question: Why have you proposed legislation to abolish End Stage Renal Disease Coordinating Councils?

Answer: We have proposed to eliminate the ESRD Coordinating Councils (Networks) because we believe they have been ineffective in assuring quality care and controlling costs. Additionally, we view them as an intrusive regulatory mechanism inconsistent with increasing competition in the health care sector.

MEDICAID

Question: Why do Wisconsin and Illinois expect lower hospital cost inflation rates that do other States?

Answer: The Wisconsin assumption was, according to the justification accompanying the State's estimate, based upon economic assumptions supplied by a private firm. It was not clear whether this low rate was the net rate after actions the State was proposing to take to control costs or it was the rate projected with no restraining action on the part of the State. Illinois expected to actively control hospital cost increases to the 2 percent rate. The justification accompanying the State's estimate was, however, not specific as to the means of achieving that rate.

Question: Yet, Wisconsin expects an extraordinary rate of increase in physician services. What is driving that estimate?

Answer: The physician cost increase in Wisconsin between 1983 and 1984 is 5.4%. The 54% reflected in the table on page 24 is a typographical error. The 5.4% increase factor is consistent with the low assumptions about price increases in other services.

MEDICAID

Question: What savings are projected to be achieved from: a) the voluntary copayment provision of the Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982? b) the mandatory copayment proposals.

Answer: The estimate for the mandatory copayment assumed that for the $249 million saved in FY 1984 that $100 million will be from the offsetting collection of the copayments and $149 million will be from the reduced utilization of inappropriate services. The TEFRA optional copayment proposal is expected to save $90 million in FY 1984, of which $54 million was assumed to be from the offsetting collection of the copayments and $36 million was attributed to reduced utilization.

MEDICARE

Question: How much of a change in hospital cost inflation do you anticipate from implementation of prospective payment?

Answer: Prospective payment will result in no reduction in hospital cost inflation in FY 1984 and FY 1985 beyond that already reflected in the budget, since the legislation requires that prospective payment be budget neutral. After FY 1985, prospective payment levels will be determined by the Secretary of HHS, taking into consideration in the recommendations of a commission of experts. We do anticipate that the movement from cost based reimbursement to prospective payment will have a positive effect on increasing hospital efficiency and thus reduce inflation in this sector.

RETURN OF EXPENDITURES FOR PAYMENT SAFEGUARDS

Question: Please provide the sliding scale table showing the point of diminishing returns associated with payment safeguard activites.

Answer: The Health Care Financing Administration (HCFA) generally expects an overall return of $4 for every $1 invested in payment safeguards. The return on the first dollars invested will be the highest, because when relatively few dollars are available, they tend to be utilized on the most obvious cases of excess utilization and inflated cost reports. As more dollars are employed in payment safeguards, the difficulty of identifying unnecessary services and nonallowable costs becomes greater, so relatively greater administrative costs are incurred to achieve additional program savings. Because so many variables are involved (inflation, productivity, contractor personnel changes, etc.), a single sliding scale does not exist for measuring return on investment for various safeguard activities. In order to maximize the return on HCFA's investment in program safeguards, we are allowing the Medicare contractors to design the specifics of their medical review and utilization review activities (MR/UR) to reflect the utilization patterns in their local areas. Data on actual returns on investment for each contractor will be gathered and evaluated.

MEDICAID SURVEY FUNDING

Question: On Page 19 of your justifications you indicate that you expect to spend $35,153,000 to support State Medicaid survey and certification activities in Fiscal Year 1984. However, the table on page 21 indicates the Federal government will spend $36.3 million next year for State certification. Will you reconcile those figures for us?

Answer: On Page 19, it is indicated that the FY 1984 obligational authority required to support Medicaid survey activity would be $35,135,000. The estimate on page 21 in the amount of $36,300,000 represents States estimates. The difference of $1,165,000 is the offset/rebate adjustment provision as outlined under Section 2161 of the Omnibus Reconciliation Act of 1981. The amount on page 19 includes this adjustment to States' estimates while the amount on page 21 does not.

Question: State certification costs are expected to rise by $8.9 million between 1982 and 1983 yet you show a projected decline in those costs of $5.7 million 1984. Can you tell us why?

Answer: In FY 1983, the estimate for Medicaid survey activity was increased by $8.9 million over the FY 1982 level to comply with the six-month moratorium on deregulation of skilled nursing and intermediate care facilities as outlined in Section 135 of the Tax Equity and Fiscal Responsibility Act of 1982 (P.L. 97-248). Also, the Congress subsequently prohibited the Department from implementing revised changes for an additional 120 days after this provision expires.

MEDICAID COST CONTROL - WISCONSIN

Question: I was interested to note that on page 23 of your justifications you indicated that Wisconsin and Illinois are exceptions to the rule that most of the States with the largest Medicaid programs are expecting double digit inflation in hospital prices to continue. Wisconsin has projected inflation to be at 7 and 6 percent in FY 1983 and FY 1984 respectively and Illinois expects to hold price increases to 2 percent in FY 1983. What makes these two States the exception to this rule?

Answer: According to the justification accompanying the State's estimate, the Wisconsin assumption was based upon economic assumptions supplied by a private firm. It was not clear whether this low rate was the net rate after actions the State was proposing to take to control costs or it was the rate projected with no restraining action on the part of the State. Illinois expects to actively control hospital cost increases to the 2 percent rate. The information supplied along with the State's was, however, not specific as to the means for achieving that rate.

WISCONSIN - INCREASED PHYSICIANS COSTS

Question: If the table on page 24 of your justification is correct, physicians costs in Wisconsin under the Medicaid program will increase by 54 percent between 1983 and 1984. Can you explain this huge one-year increase?

Answer: The 54 percent figure is a typographical error and should have been 5.4 percent. That is consistent with the low assumptions about price increased in other services.

MEDICAID--HOUSEKEEPING SERVICES

Question: More than 2 years ago, your Inspector General (IG) found that a State charged housekeeping services--such as shopping and ironing--for certain Medicaid recipients without first requiring that they be medically necessary. One State filed claims totaling $15 million over a 15-month period and the IG estimated that similar improper claims could run as high as $30 million annually nationwide. The IG's September 30, 1982 report indicated that no action had been taken to correct the problem. Do you have any plans to pursue this issue?

Answer: HCFA agreed with the IG's finding that purely nonmedical housekeeping services were not intended to be covered as personal care services under Medicaid. However, the Office of the General Counsel issued an opinion indicating that the existing, broadly-worded personal care services regulations could not sustain a proposed disallowance, as even the services in question could be considered to meet the minimal and nonspecific requirements contained in the regulations. HCFA then began to work on implementing the IG's recommendation that the regulations be revised to provide the specificity necessary to convey intended policy. HCFA considered various alternatives or revising the personal care services regulations; however, before this work could be completed, the home and community-based services waiver provision (section 2176 of P.L. 97-35) was enacted, necessitating a reassessment of the personal care services regulations in light of the new legislation. HCFA plans to complete this reassessment shortly, and subsequently, to propose revisions to the personal care services regulations in a manner consistent with the home and community-based services waiver provision.

MEDICAID PSYCHIATRIC SERVICES-POSSIBLE ABUSES

Question: What about Medicaid benefits for social and recreational services masquerading as psychiatric therapy? Procedures at one facility visited a few years ago called for Medicaid to pay for psychiatric services provided in the patient's room when the only documentation found in the case file by auditors to support such billings were entries such as: "patient attended basketball game" -- "patient played checkers". Similar abuses have been found in nursing homes and the Inspector General (IG) has recommended that you determine the extent of these problems and revise your regulations to further define covered psychiatric services. as of September 30 there has been no progress in implementing the IG's recommendation. Why haven't you moved ahead in this area?

Answer: We are aware of some interest in sharpening the definition of billable encounters and in increasing the specificity of case record documentation. However, we question the long-term utility of such actions because the basic nature of psychiatric services precludes highly exacting reporting of day-to-day

progress. Most often, patients are receiving continuing therapy that only gradually shows results. Realistically, there may be little more to insert into a case record on a day-to-day basis than the documentation that the IG's report found questionable.

MEDICAID--DRUG ABUSE

Question: The Inspector General reports that in a number of States, a small but significant number of Medicaid recipients overuse drug benefits. Frequently, these drugs end up being sold to other drug abusers. Many States, particularly those with major urban areas, have no drug restriction programs at all under Medicaid. The Inspector General recommended that HCFA work with States to implement such programs. Although you agreed in principle, as of September 30 of last year nothing had been done. Have you taken any action since then to meet the problem?

Answer: Under the waiver provisions of section 1915 (b) States may:

(1) implement a case management system which restricts the provider from or through whom an individual can obtain primary care services if the restriction does not substantially impair access to services of adequate quality where medically necessary; and,

(2) restrict providers from or through whom an individual can obtain services to providers or practitioners who meet, accept, and comply with the reimbursement, quality, and utilization standards under the State plan. These standards must be consistent with access, quality, and efficient and economic provision of covered care services. The restriction must not discriminate among classes of providers on grounds unrelated to their demonstrated effectiveness and efficiency in providing those services.

We believe section 1915 (b) provides adequate authority for the States to address any problems found to exist in their respective Medicaid programs regarding prescription drug abuse.

PACEMAKERS

Questions: On September 30 the Inspector General (IG) made a tentative finding that more efficient procurement of pacemakers could result in annual Medicare savings of over $64 million. Auditors compared prices for 2804 pacemakers bought by 25 hospitals in 10 States for Medicare patients with the prices available to Federal agencies under the General Services Administration's (GSA's) multiple award Federal supply Schedule. Most of the procurements under the Schedule are for Veterans Administration (VA) hospitals. The auditors found that under Medicare, hospitals paid an average of $591 more than GSA paid under the Supply Schedule contracts. What arrangements have you made to obtain a more favorable price for pacemakers?

Answer: We agree with the IG's recommendation that the Department of Health and Human Services establish prospective cost limits on the amounts hospitals would be reimbursed for pacemakers.

We believe that the inclusion of Pacemaker implantation and replacement under the recently enacted prospective reimbursement system will encourage hospitals to procure such medical devices more prudently. In addition, we recently issued general medical necessity guidelines for cardiac pacemaker implants in order to assure a measure of national consistency in the coverage and processing of claims for these devices. We are also considering other approaches to further limit the reasonable charge for medical devices, e.g., pacemakers that physicians furnish patients.

Future activities include consideration of total cost limits, and carrier review of pacemaker claims to assure proper warranty credit of faulty pacemakers by establishing payment edits keyed to device replacement. We also plan to develop specific medical necessity guidelines for the new, high-technology pacemakers, as well as guidelines for post-implant monitoring of pacemakers.

In undertaking these initiatives, HCFA will be working closely with the Public Health Service to assure maximum coordination and pooling of resources. We have also taken steps to assure close coordination with medical specialty societies, such as the American College of Cardiology, as well as the pacemaker industry itself, in order to draw upon their advice and expertise.

MEDICARE SAVINGS

Question: You state on page 95 of your justifications that the Medicare Administrative Reform Initiative (MARI) saved $63 milion in FY 1982 in Medicare contractor operations. Since estimated contractor funding levels in 1982 were about $704 million and actual costs were $711 million, what does the $63 million in savings represent and what base amount should it be deducted from?

Answer: The $63 million MARI savings have been taken into account in the FY 1982 base period and are factored into the FY 1983, FY 1984 and FY 1985 claims payment amounts. This means the FY 1983 claims payment has already been reduced by $63 million after consideration of workload increases, inflation and productivity gains. The Health Care Financing Administration plans to continue the MARI as long as cost savings can be achieved. This is reflected by additional cost reductions of $30.9 million and $21.0 million in FY 1983 and FY 1984, respectively.

MEDICARE CONTRACTOR COSTS

Question: Although Medicare contractor costs increased by about $20 million--approximately 3 percent -- between 1981 and 1982, they are scheduled to increase by a whopping $109 million -- 15.3 percent --between 1982 and 1983. Doesn't this indicate that your Medicare Administrative Reform Initiative (MARI) has failed in its objectives?

Answer: A large portion of this increase involves the additional $45 million Congress appropriated for audit and medical review. It does not indicate that MARI has failed. As indicated in the FY 1984 budget request, HCFA has carried $63 million in cost savings into FY 1983 and has also estimated that another $30.9

million will be saved during this period. The FY 1982 contractor actual costs were slightly under budget. Without the MARI, FY 1982 contractor costs would have been substantially higher and HCFA would have had to request additional funds.

Question: (If the response refers to the $45 million for contractor audits and medical reviews.) Even if we deduct $45 million for the growth in Medicare contractor costs between 1982 and 1983 we end up with cost growth of $64 million or 9 percent. Why this spurt in costs following cost growth of 3 percent the year before and projected cost growth of 2 percent next year?

Answer: The 9 percent in contractor administrative cost, after adjusting for the $45 million for audits and medical review made available under Section 118, is primarily due to a resumption of normal claims processing operations, which were constrained under the FY 1981 and FY 1982 budgets. Another factor which impacted the FY 1983 increase was the cost of implementing various Tax Equity and Fiscal Responsibility Act provisions, other than Section 118. These include claims processing activities involved with Section 101 (Hospital Payments), Section 103 (Nursing Differential), Section 113 (Surgical Assistants), Section 116 (Working Aged), and Section 122 (Hospices).

MEDICARE PROGRAM MANAGEMENT

Question: Once again this year you are requesting the transfer of $45 million out of the Medicare Trust Fund under Section 118 of the Tax Equity and Fiscal Responsibility Act of 1982 to carry out provider cost audits and reviews of medical necessity. The Congressional Budget Office has estimated that the expenditure of $45 million a year for three years under this authority will save $750 million in unnecessary medical care costs. Can you tell us how much in total you have budgeted for medical necessity reviews this year and next and indicate how much you obligated for this purpose last year?

Answer: In FY 1982, HCFA spent approximately $18 million on medical review. HCFA has budgeted $38.0 million for contractor medical reviews in FY 1983 and $35.7 million in FY 1984. The dollar reduction is not because of a decreased emphasis on medical review. The new Peer Review Organizations (PRO) will be assuming a large portion of the intermediaries' medical review activity in FY 1984.

Question: How much money was saved as a result of medical review last year and how much do you anticipate saving in 1983 and 1984?

Answer: We have projected a savings ratio of $3 to every $1 spent for Part A reviews. On the Part B side, the projected ratio is $5 in savings for every administrative $1 spent. FY 1982 savings totalled approximately $75 million. Savings of over $150 million are expected to be achieved in both FY 1983 and FY 1984 as a result of medical review. Our preliminary information shows that the projected savings ratios will be met.

Question: Why wouldn't it be cost effective to increase funding for medical necessity reviews?

Answer: Fiscal year (FY) 1984 will be a major transition year for the intermediaries. The Peer Review Organizations (PROs) are scheduled to be completely in place by the end of FY 1984. Hospitals are phasing into prospective payment during the same year. We believe that it would not be cost effective to build up intermediary medical review staff in that year. We believe that carrier FY 1983 performance in medical review needs additional evaluation before requesting higher funding levels.

MEDICARE -- HOME HEALTH CARE

Question: In May 1979 the General Accounting Office (GAO) issued a report indicating that home health care costs under the Medicare program varied widely and that no cost limits had been established by the Federal Government. Apparently the Administration implemented a uniform cost reporting methodology 2 years ago, but as of March 1, you were in the process of developing a data base using the methodology and planned to analyze the data base to determine if some limits can be established. Its been almost 4 years since the GAO report came out. Why haven't you been able to resolve this issue in that time?

Answer: "Section 223" limits on per visit costs of home health agencies (HHAs) have been in effect since July 1, 1979, and have been revised and updated yearly since that date. Prior to the single method costs reporting regulation effective October 1, 1980, HHAs used several different cost finding methods which allowed us to make cost settlements and apply the cost limits, but restricted our ability to create a uniform data base for policy evaluation purposes. The data from the revised cost reports is presently being extracted and will be used to conduct the kinds of analyses on components of HHA costs (e.g., administrative costs) that GAO suggested in their 1979 report.

Question: When will you make a final decision on regulating the costs of home health care?

Answer: We will make recommendations as to the appropriateness of regulation changes after we evaluate the uniform data base, the impact of the Tax Equity and Fiscal Responsibility Act of 1982 change to single cost limits, and the possibility of developing a prospective payment system for HHAs.

INTERMEDIARY HOME HEALTH REVIEW

Question: Section 2152 of the Omnibus Budget Reconciliation Act of 1981 required HHS to establish guidelines for home health care and to implement the guidelines through postpayment coverage reviews or by other means. Apparently your response was to require contractors to perform medical coverage audits of home health services. Can you tell us, on a national basis, what those audits have disclosed?

Answer: The providers are chosen on the basis of volume ranking (top 10%), new provider status, and nonfavorable waiver status.

The audits indicate an overutilization of medical services and a need to obtain more definitive information for claims review.

Question: How many claims and how much in payments have been denied as a result of the home health coverage compliance audits.

Answer: The purpose of the home health compliance audits is to identify problem areas or providers, not to deny claims. The Health Care Financing Administration (HCFA) and its Medicare intermediaries use the information gained from compliance audits to modify provider behavior. We do not, therefore, maintain a record of claims denied.

Question: I understand that preliminary data from the audits show an overutilization of medical services and a failure in some instances to conduct medical necessity reviews. What steps is HCFA taking to correct the overutilization of medical services and insure that intermediaries conduct medical necessity reviews?

Answer: The Health Care Financing Administration (HCFA) will require all intermediaries to collect specific medical information at regular intervals for home health claims review, and has included standards for conduct of medical review Contractor Performance Evaluation Program criteria.

END-STAGE RENAL DISEASE PROGRAM

Question: On January 21 the General Accounting Office (GAO) issued a report on the kidney dialysis program that concluded requiring the purchase of the necessary equipment by Medicare users as an alternative to renting the equipment could save on the order of $20 per treatment. The report also found that in some cases Medicare patients paid almost twice as much for supplies as the amount paid by some facilities.

The report concluded that Medicare should be able to negotiate a supply price at least equal to the price of Veterans Administration pays and that Medicare should require the purchase of equipment by patients dialyzing for prolonged periods. What steps are you taking to implement these recommendations?

Answer: The GAO recommendation was that the Secretary direct HCFA to require the purchase of dialysis equipment by home patients dealing directly with suppliers except in cases where to do so would place an undue hardship on the patient or where purchase can be shown to be more costly.

We concur with the objective of this recommendation. We believe, however, that implementing this recommendation would have limited application. Additionally, we have reservations about the prudence of purchasing large amounts of dialysis equipment. This is not to suggest, however, that we are not supportive of home dialysis. In fact, the composite rate will provide incentives for facilities to encourage home dialysis, and to some extent obviating the purchase decision.

The GAO concluded that the Medicare program could save a substantial amount of program dollars if it required a home hemodialysis patient to purchase a dialysis machine instead of renting it at the time the beneficiary initiates home dialysis. Based on GAO's data, the purchase price plus the annual maintenance cost would be offset in only 21 months when compared to the average rental machine payments. The GAO further concluded that if the cost of money is considered, the average payback period is increased from 21 to approximately 24 months. The GAO cites 54 months as the average length of time that a dialysis patient remains on dialysis and implies that his figure is also applicable to a home dialysis beneficiary. Their estimated savings for this recommendation is the difference between the 54-month and the 21-month payback time.

The Health Care Financing Administration disagrees with the data assumptions that are the basis for this recommendation. Further, the recommendation does not consider the problems that would result from implementation of such a regulation. First, the cost of money is a legitimate cost and should be included in any cost/benefit analysis. Therefore, we will assume 24 months as the GAO's base payback period. Second, there are more costs involved in the question of purchase versus rental of dialysis machines than those mentioned in the GAO's report. For example, there is the cost of purchasing ancillary equipment such as chairs, scales, etc.; the cost of modifications (electrical and plumbing) to the patient's home; in addition, most manufacturers charge an installation fee and a freight charge. These costs should have been considered because they directly influence the length of the payback period; some of these costs, especially installation and freight, are routinely included in the normal rental payments. In addition, GAO implies that the average home dialysis patient stays on home dialysis for 54 months. We would like to point out, however, that the average of 54 months applies to all dialysis patients (home and in-center). While data is difficult to obtain, a more telling statistic for purposes of this discussion is the median length of time that a home dialysis patient remains on home dialysis. Information we were able to obtain indicated that the median is between 18 and 30 months. Therefore, requiring lump-sum purchase of a dialysis machine would not seem practical in the majority of cases and would not save program dollars.

The average total cost of installing a new dialysis machine in the patient's home is over $12,000. The beneficiary's coinsurance liability would be a lump sum payment of at least $2,400 in addition to the ongoing liability for supplies, physician fees and home support services. Most home dialysis patients would not be able to meet such payments.

In conclusion, we believe the current instructions include adequate provision for beneficiaries to purchase dialysis machines, when appropriate. However, based on available program data, it does not appear that the purchase of dialysis machines by all beneficiaries is the most cost-effective and practical payment method in the majority of cases.

Question: As you know, the Omnibus Budget Reconciliation Act required the Secretary of Health and Human Services to establish by regulation prospectively determined Medicare reimbursement rates for kidney dialysis in order to encourage the use of the least costly treatment procedures.

Although a proposed regulation was published in the Federal Register on February 12, 1982, as of March 1st of this year the final regulation had not been issued. What has caused the delay and when can we expect the legislative mandate to be carried out?

Answer: Secretary Heckler signed these regulations on March 24, 1983. After the Secretary's signature, they were sent to the Executive Office of Management of Budget. The EOMB is currently reviewing the regulations. The regulations will be published as soon as this review is completed.

Question: When you published the proposed End-Stage Renal Disease regulation you estimated that it would save $130 million in fiscal year 1983 if implemented by May 1 of 1982. Do you still believe that a prospectively determined reimbursement rate could achieve savings of this magnitude?

Answer: The estimate of $130 milion savings published in the February 12, 1982 Federal Register was composed of two parts. Twenty-five million dollars of the $130 million was an actuarial estimate of the savings attributed to the regulation. The remainder, $105 million, was the amount which could be saved by tightening the ESRD facilities exceptions process currently in effect. We still believe that savings of this magnitude can be achieved, although we now estimate that the first year impact (FY 1983) will be reduced to $25 million due to delayed implementation. Of this $25 million, $5 million is attributable to the regulation itself while $20 million will be the result of tightening the exceptions process. In FY 1984 this savings will rise to about $180 million of which $35 million is directly attributable to the new rule for reimbursement.

TRAVEL COSTS

Question: Your travel and transportation obligations will be slightly over $4 million during this fiscal year. In FY 1984, that amount would be increased to $4,323,000, or putting it another way -- $1,047 per full time HCFA employee. Why can't you reduce these expenses?

Answer: Travel funds have decreased $1,818,000 between fiscal years 1980 and 1983. HCFA has had to absorb this decrease in a climate where travel costs are rising dramatically due to inflation. The savings of $1,818,000 since FY 1980 were attributable to a series of positive management decisions undertaken by HCFA to curtail all but mandatory travel. For example, employees were asked to utilize the teleconferencing equipment in lieu of travel. Travel related to training and conferences was also restricted.

The increase in FY 1984 is for inflation only. Of the total travel request of $4,323,000, over 67 percent will be required to conduct program-related travel in the HCFA Regional Offices in such areas as:

- o Contractor Performance Evaluation Program - On-site reviews of a random sampling of claims are necessary to evaluate the efficiency of Contractors' operations and to ensure compliance with regulations and program requirements.

- o Medicaid Quality Control - On-site visits by regional staff are required to detect errors in sample claims reviewed by States and to validate State-determined Medicaid error rates.

- o Cost Report Evaluation Program - Travel funds are essential to review intermediary settlements of institutional provider cost reports to assure accuracy in the allocation of costs to Medicare and the disallowance of non-covered costs.

- o State Agency Evaluation Program - Travel funds are required to review the States' performance in the survey process. Travel is also required for on-site entrance and exit interviews for the Cost Report Evaluation Program and State Survey Agency Evaluation Program.

- o State Agency and Contractor Budget Process - Travel is required for budget negotiations and follow up discussions with State agencies and the Medicare contractors. The primary purpose for this travel is for the regional staff to review and analyze specific contractor needs, negotiate upcoming year funding levels, and discuss program objectives with the contractors.

In addition to regional staff travel requirements, some travel is performed by HCFA's central office staff. Major areas include the on-site monitoring of the implementation and maintenance of the Uniform Hospital Bill (UB-82) and the HCFA Common Procedure Coding System (HCPCS). Travel funds are also required for frequent trips to numerous HCFA fiscal intermediaries and carriers, and to consult with other organizations involved in the program.

The implementation of the Hospital Cost Report Information System (HCRIS) requires on-site conferences with contractors to resolve issues dealing with implementation costs, Automated Data Processing (ADP) systems modifications and reporting requirements.

CONSULTANT SERVICES

Question: According to material provided to the Committee on March 14, your consultant services budget will increase by almost 40 percent to $2,349,000 next year. Can you tell us why an increase of this magnitude is necessary?

Answer: These funds are not for the purpose of hiring individuals. Rather, they are for contracts which will be used in the Research area for the continuation of certain Congressionally mandated projects started in FY 1983 such as the "Rural Swing Bed" program, for Medicaid related projects, and for the hospice program mandated by Tax Equity and Fiscal Responsibility Act (TEFRA).

In addition, contracts will be used in the State Certification program to provide advice on the development, implementation and assessment of experiments in the use of different methodologies to determine compliance with condition of participation and in the area of Administrative Costs, for the Automated Data Processing/Telecommunication initiative.

FINANCIAL AUDITS

Question: On page 109 of your justification you indicate that HCFA staff cleared over 300 General Accounting Office (GAO) and Inspector General (IG) audits with financial findings totaling more than $150 million. How much of this amount represented actual recoveries?

Answer: For the 300 GAO and IG audits cleared during fiscal year 1982, we identified inappropriate payments of $137,217,834. Because the audit findings are subject to appeal, actual recoveries are often not made until well after the audit is cleared. Therefore, we do not yet have data on amounts actually recovered as a result of these audits.

HCFA-RESEARCH DEMONSTRATION AND STATISTICAL ANALYSIS

Question: On page 112 of the justifications you estimate savings of $2 billion in 1982 from demonstrations, experiments, and research projects. However, only $635 million in 1982 savings are identified on page 85. Can you tell us how you achieved the remaining $1.4 billion in savings?

Answer: The justification should have stated that the full $2 billion program savings is estimated for FY 1984, not FY 1982. This can be found on page 85 of the justification. These savings will occur in the areas of total cost limits, elimination of private room and nursing differentials under Medicare, and malpractice insurance changes.

OTHER SERVICES

Question: The biggest increase proposed in your administrative costs for FY 1984 is "other services" which is up by more than 36 percent for the current level. What's included in this activity? Let us have a detailed breakdown for the current fiscal year as well as how you plan to use these funds next year.

Answer: The "other services" consist of the following on-going items:

- Automated Data Processing contracts, such as programming and data entry services for $2.0 million;

- General operating expenses for the Agency such as contracts, General Services Administration (GSA) guard services, training of personnel and maintenance agreements totaling $8.0 million;

- Interagency agreements with other Federal agencies for $1.0 million;

- Direct Reimbursement audits for $1.3 million; and

- The Premium Collection "Lock Box" contract for $2.0 million.

The increases in this area are for the following:

- The Automated Data Processing/Telecommunications System acquisition plan for $5.0 million;

- The support contracts for needed services related to the loss of skilled personnel, such as computer programming, systems analysis and actuarial services totaling $1.3 million;

- Funds for the Equal Access to Justice cases for $1.0 million; and

- Inflation of $.7 million.

RESEARCH BUDGET

Question: What is included in the Other Services you propose to finance under research, demonstration and evaluation projects? You are proposing $13.8 million for this activity next year. Let us have a detailed breakdown of these expenses for fiscal year 1983 as well as fiscal year 1984.

Answer: The HCFA research, demonstration and evaluation program is supported essentially through grants and contracts. The contract portion of the budget falls within the Federal Government's Other Services object class. The range of contract supported activities proposed in FY 1984 is basically similar to the FY 1983 range.

BASIS FOR MORATORIUM

Question: Why is there a Congressional moratorium on implementing your prosposal to modify certification procedure for providers and suppliers of services?

Answer: The moratorium was imposed by Congress in response to the concerns raised by their constituents. There was a perception expressed by many commentors that the proposed refinements to the survey and certification process would weaken the Department's ability to enforce compliance with health and safety requirements. The Senate and House Committees on Aging and other individual members of Congress wanted additional time to study the proposals.

Question: Are any expenses incurred by the Task Force on Regulatory Reform? If so, what are they?

Answer: The Task Force is composed of senior level HCFA staff who, as part of their regular duties, personally participate in regulatory reform deliberations. Consequently, there are no additional expenses incurred by the Task Force above and beyond individual salaries which are already part of the budget.

ADMINISTRATION -- FY 1984 BUDGET

Question: On the last page of your justification you list your 15 administrative functions with positions for fiscal years 1983 and 1984. For the record please provide the 1983 and 1984 budgets of each of these functions.

Answer: HCFA does not prepare its budget by functions. The table below was prepared by distributing total obligations on a per capita basis.

	FY 1983	FY 1984
1. Program Administration	$ 8,774,070	$ 9,645,771
2. Medicare/Medicaid Financial Operations	16,972,064	18,658,234
3. Medicare/Medicaid Agent Performance Assessment	12,895,224	14,176,361
4. Quality Control	19,276,366	18,268,506
5. Program Validation	5,760,753	6,333,082
6. Maintenance of Health and Safety Standards	17,548,140	19,291,543
7. Regulations Development and Reform	4,918,797	5,407,478
8. Research, Demonstration and Statistical Analysis	13,028,164	14,322,509
9. Direct Reimbursement	10,325,042	5,699,774
10. Program Systems Development and Maintenance	32,082,962	35,270,396
11. Program Instructions/ Technical Assistance	14,357,569	15,783,989
12. Legislative and Congressional Affairs	2,525,869	2,776,813
13. Program Communications and Beneficiary Services	12,230,521	13,445,621

	FY 1983	FY 1984
14. Administrative Support	16,883,437	14,663,521
15. Executive Direction	6,647,022	7,307,402
Total Obligations	$ 194,226,000	$ 201,051,000

ADMINISTRATION - ADP/TELECOMMUNICATION SYSTEM

Question: You plan to spend $5 million in fiscal year 1984 for the completion of the major ADP/Telecommunication System Acquisition plan initiated late in fiscal year 1981. How much will you have spent on the plan through the end of fiscal year 1983?

Answer: Through fiscal year 1983 we have spent approximately $1 million in support of the Major Systems Acquisition project. Approximately $500,000 went to a consultant services contract for the development of alternative systems design concepts. The remainder was used for related studies and to acquire automatic data processing/telecommunications (ADP/TC) hardware and software to support pilot projects in the areas of office automation and data base management systems (DBMS).

Question: Can you tell us now, or at least give us a rough idea, how much it will cost to implement the plan?

Answer: It is difficult to say how much it will cost to implement the plan since costs will vary in direct proportion to the overall system design selected by HCFA. Under consideration are issues such as:

-- a direct access system for providers (e.g., the System to Provide Immediate Data on Eligibility for Reimbursement (SPIDER));

-- a regionally-distributed data base system vs. continued centralized operations; and

-- on-line vs. batch processing.

Decisions on the design and information flow issues, and the selection of the long-term ADP/TC environment design for HCFA, are expected to be finalized by mid-1985, as a result of a consultant's findings and recommendations. At that time we will be in a better position to provide projected costs and savings figures.

Question: Are you in a position to tell us how much your proposed ADP/Telecommunications systems acquisition will save the government over the life of the system and when its benefits will start to balance its costs?

Answer: As mentioned in the previous statement, to project actual costs and savings in this early stage of such a long-range project, would be difficult. Current plans include making short-range enhancements to current systems from which benefits and savings could begin accruing to the government as early as mid-1984. Benefits and savings would increase as each phase is implemented until maximum annual savings are realized.

SUBCOMMITTEE RECESS

Senator WEICKER. We'll now stand in recess until Monday, April 11 at 8:30, and then we'll hear testimony from the Office of Human Development Services.

[Whereupon, at 9:50 a.m., Friday, April 8, the subcommittee was recessed, to reconvene at 8:30 a.m., Monday, April 11.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1984

MONDAY, APRIL 11, 1983

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, D.C.

The subcommittee met at 8:30 a.m., in room SD-116, Dirksen Senate Office Building, Hon. Lowell P. Weicker, Jr. (chairman) presiding.

Present: Senators Weicker and Proxmire.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF HUMAN DEVELOPMENT SERVICES

STATEMENT OF DORCAS R. HARDY, ASSISTANT SECRETARY FOR HUMAN DEVELOPMENT SERVICES

ACCOMPANIED BY:
JOSEPH A. MOTTOLA, DIRECTOR, OFFICE OF MANAGEMENT SERVICES
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OFFICE OF COMMUNITY SERVICES

STATEMENT OF HARVEY R. VIETH, DIRECTOR

Senator WEICKER. The subcommittee will come to order.

Today we will hear testimony from the Assistant Secretary for Human Development Services, Ms. Dorcas Hardy.

We will also hear from Dr. Harvey Vieth, who leads the Office of Community Services, the successor agency to the Community Services Administration.

These two agencies have a wide variety of programs that serve many of the most vulnerable groups in our society, including abused and neglected children, runaway youth, the developmentally disabled, older Americans, Indians, and impoverished families.

Despite the increased need for many of these services due to the long recession and continuing high unemployment, your budgets call for cuts in virtually all areas—the major exception being Head Start, where there is a $62 million increase.

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Ms. Hardy, please proceed with your explanation of the administration's fiscal 1984 appropriations requests for human development programs, and after your opening remarks we will then hear any comments Dr. Vieth may care to make.

Ms. HARDY. Thank you, Mr. Chairman. I have submitted my statement for the record, but I would like to make some introductory comments which will provide the framework for our budget requests.

[The statement follows:]

STATEMENT OF DORCAS R. HARDY

I am pleased to appear before you today to discuss the fiscal year 1984 budget request for programs administered by the Office of Human Development Services. A total of $5,340,192,000 is requested to support a variety of social programs which serve children and youth and their families, the elderly, those who are developmentally disabled, and native Americans. Of the total requested, $2,500,000,000 is requested for the social services block grant appropriation; $2,193,446,000 is requested for the human development services appropriation; $9,250,000 is requested for the human resources research and demonstration appropriation; and $601,496,000 is requested for the family social services appropriation. No funds are requested for the work incentive program. The total requested for all programs administered by the Office of Human Development Services represents 92 percent of the comparable amounts available for these activities in fiscal year 1983. The reduction is consistent with the President's budget policy to limit Federal spending. Service levels supported in fiscal year 1983 will be maintained to the extent possible. Support for discretionary activities which do not provide services has been substantially reduced.

A level of $2,500,000,000 is requested for the social services block grant to continue support for a variety of social services through the States. The amount requested represents the full authorization for this program in fiscal year 1984. Services which a State may choose to provide may include, but are not limited to: child and adult day care services, protective services, foster care, transportation, training, information and referral, counseling, delivery of meals, and health support. Because no funds are requested for the community services block grant, an amendment to the social services block grant will be proposed to allow States to carry out most activities previously carried out under the community services block grant.

A level of $2,193,446,000 is requested for the human development services appropriation. This appropriation includes programs for children and youth and their families, the elderly, those who are developmentally disabled, and native Americans.

For the Head Start program, $1,050,650,000 is requested to support the delivery of comprehensive child development services to 424,900 preschool children and their families, an increase of 29,100 children over the 395,800 children who received Head Start services in fiscal year 1983. The expansion effort will focus on innovative and cost-effective ways of providing Head Start services. In addition, funds which are estimated to be the value of the Head Start share of the U.S. Department of Agriculture's child care food program have been included in the Head Start request in an effort to simplify program management. An amendment will be proposed to make Head Start ineligible for child care food funds from the Department of Agriculture.

For the Administration on Aging, a level of $997,906,000 is requested. The request will provide a full range of social and nutrition services to approximately 3.2 million elderly persons. This request includes a proposed transfer to the aging program of the Department of Agriculture administered food commodities program for the elderly. This transfer will simplify program administration at both Federal and State levels. In addition, legislation is proposed to allow the Office of Human Development Services to fund activities currently administered by the Department of Labor under the authority of title V of the Older American's Act.

For developmental disabilities programs a level of $41,298,000 is requested. The program will continue to coordinate, monitor, and evaluate services provided to the developmentally disabled; to provide for systems of protection and advocacy of individual

rights of persons who are developmentally disabled; and to provide support for university affiliated facilities. Appropriation language has been added to cap States' entitlement to State grant funds notwithstanding holdharmless requirements prescribed in the law.

For native American programs, $22,466,000 is requested to promote social and economic self-sufficiency for American Indians, Alaska Natives, and native Hawaiians. There was a proposed initiative to administer the Administration for Native Americans' financial assistance grants to federally recognized Indian tribes through the Bureau of Indian Affairs, beginning April 1, 1983. However, the recently enacted jobs bill, Public Law 98-8, requires that these financial assistance grants continue to be administered by the Department of Health and Human Services. Consistent with Public Law 98-8, the Department no longer plans on making this change during fiscal year 1983. We will continue to work closely with the members of this committee and the Congress in your consideration of this proposal as part of our fiscal year 1984 program. Assistance to nonfederally recognized tribes and organizations will be phased out by 1986.

An amount of $63,892,000 is requested for human development services program direction. These funds will provide effective and efficient management of all programs administered by the Office of Human Development Services.

A level of $9,250,000 is requested for the human resources research and demonstration appropriation and will support research, demonstrations, training, and evaluations in the areas of child welfare, day care, youth, child and family development, child abuse and neglect, and cross-cutting research, including technology transfer. The amount requested represents 42 percent of the comparable amounts available for these activities in fiscal year 1983. This reduction is consistent with administration policy to minimize costs in areas which do not provide direct services.

A level of $601,496,000 is requested for the family social services appropriation. Funds requested will continue to provide assistance to States to strengthen the family unit, to reunify children with their families, or, where this is not possible, to find suitable adoptive homes for them. These funds will support the child welfare services program, and the foster care and adoption assistance programs. Legislation is proposed to cap the foster care program at a level of $440,170,000 in 1984 and thereafter. This level represents our estimate of fiscal year 1984 claims. Enactment of this legislation will eliminate the open-ended entitlement nature of this program, resulting in reduced Federal spending in 1985 and beyond. In addition, the cap will provide incentives to States to remove children from institutions and place them in better and less expensive forms of foster care and to provide services to preclude the need for foster care placement.

Thank you, Mr. Chairman, My colleagues and I will be happy to answer any questions you and the committee may have.

STATEMENT OF DR. HARVEY R. VIETH

Mr. Chairman, members of the committee, I am pleased to appear before you today to discuss President Reagan's fiscal year 1984 budget request for the community services block grant program. The Office of Community Services fiscal year 1984 request does not include funding for the community services block grant program. the request of $2,852,000 covers salaries and expenses of a staff of 40 full-time equivalent positions to closeout block grant and discretionary activities of prior years.

The administration is proposing in fiscal year 1984, to repeal the Community Services Block Grant Act and to clarify the authority of States to use social services block grant funds to support community services block grant activities. It is believe that this proposal will help achieve budget savings by eliminating duplication of effort currently existing with the overlapping program authorities. Both programs now provide significant services and assistance to the poor in the area of service delivery systems. for example, the fiscal year 1983 continuing resolution which provided funding for community services block grants directs that States use 90 percent of their community services allotments to make grants to entities which were eligible in 1982, that is, predominantly community action agencies. These organizations, which already provide social

services in many States under the social services block grant and other programs such as Head Start, would at the State's option, remain eligible for funding under the expanded social services block grant program.

Discretionary activities now authorized under the Community Services Block Grant Act will be transferred or considered for funding under other program authorities. The national youth sports program will be transferred to the Public Health Service whose budget request includes $5,760,000 in fiscal year 1984 to fund this program.

Other discretionary activities, including community economic development and assistance to migrant and seasonal farmworkers, may be pursued under other program authorities already existing in the Department of Health and Human Services or the Departments of Agriculture, Labor, Commerce, and Housing and Urban Development.

Mr. Chairman, that concludes my statement and I will be happy to answer any questions that you or the committee members may have.

SUMMARY STATEMENT

Ms. HARDY. We have a common goal for all of our human development services programs of social and economic self-sufficiency. We believe that a policy of sound economic growth is the best means of promoting this self-sufficiency among as many of our vulnerable populations as possible.

Consistent with this policy and this goal, the Office of Human Development Services has requested a budget that we believe helps reduce Federal spending but also reflects our commitment to maintain service levels wherever possible.

We have chosen to make reductions in programs which do not provide direct services, such as discretionary activities where programs are capable of offsetting decreases through program and management initiatives, such as in the Administration on Aging, or in programs where we believe the least impact will occur.

Our budget request for human development services is $5.3 billion. We believe we are requesting substantial resources, including, as you mentioned, over $1 billion for Head Start where there is a $62.3 million increase which is expected to expand comprehensive child development services to an additional 29,100 children, at least 10 percent of whom are handicapped.

We believe that the expansion effort in Head Start builds upon our successes this year of adding more than 15,000 children to the Head Start program through management efficiencies.

We also see the new Head Start moneys as being used not only to expand the number of children, but to allow innovative means of providing those services.

For example, we will be funding existing day care projects so that services would be expanded to include a full range of Head Start child development services.

We believe we have considered the alternatives available to us and have constructed a budget request that will maximize the efficient and effective use of our resources and the efficiency and effectiveness of our programs and how they are administered.

We also believe our requests will continue to provide those populations that we serve with needed services.

Thank you. I would be glad to answer any questions.

Senator WEICKER. I have your comments in front of me, and on page 2 it says "Because no funds are requested for the community services block grant, an amendment to social services block grant will be proposed to allow States to carry out most activities previously carried out under the community services block grant."

On page 3, "An amendment will be proposed to make Head Start ineligible for child care food funds from the Department of Agriculture."

Page 3, "This request includes a proposed transfer to the aging program of the Department of Agriculture administered food commodities program for the elderly."

Page 3, "In addition, legislation is proposed to allow the Office of Human Development Services to fund activities currently administered by the Department of Labor under the authority of title V of the Older Americans Act."

Page 3, "Appropriation language has been added to cap States' entitlement to State grant funds notwithstanding hold harmless requirements prescribed in the law."

Page 4, referring to Public Law 98-8, "the Department no longer plans on making this change during fiscal year 1983. We will continue to work closely with the members of this committee and the Congress in your consideration of this proposal as part of our fiscal year 1984 program. Assistance to nonfederally recognized tribes and organizations will be phased out by 1986."

Page 4, "A level of $9,250,000 is requested for the human resources research and demonstration appropriation and will support research, demonstrations, training, and evaluations in the areas of child welfare," et cetera.

Page 5, "Legislation is proposed to cap the foster care program at a level of $440,170,000," et cetera.

That's almost a record for proposed legislation before an appropriations committee, and I want to know if the budget is so constructed that if none of these changes are passed upon—and they won't be by this committee—that's not the job of this committee—how does that affect your budget?

Ms. HARDY. Almost $400 million of our budget is dependent upon legislation, about 7 percent of it, and we anticipate that the legislation will be submitted shortly.

Senator WEICKER. I don't know why we have to go through this repetitive exercise. But just so that nobody can plead ignorance next year, it is not the job of the Appropriations Committee to legislate.

Ms. HARDY. Correct.

Senator WEICKER. I do not consider a proper budget to be one that is constructed on the basis of speculation as to what might happen, and this is especially so in light of the fact that again these proposals have not even been placed before the authorizing committee. This obviously isn't going to change what has been done here today, but I hope we

don't see this again next year. And, as I have indicated to you, this committee will specifically take no action—I shouldn't say we won't take action. It could very well be proposed by other members of the committee. I would doubt such legislation would pass in light of Chairman Hatfield's aversion to any legislation on any appropriations bills, an aversion, I might add, I share. I have spent half of my life on the floor of the U.S. Senate fighting legislation on appropriations bills.

DEVELOPMENTAL DISABILITIES

Last year Congress rejected your proposal to cut the developmental disabilities from the basic State grant program by more than 40 percent. Is there anything new or different about this year's proposed cut of 43 percent?

Ms. HARDY. In the proposal that we are submitting through the appropriations process some of the States would receive less than the minimum allotments that are stated in the law. That is the difference.

Senator WEICKER. For the second straight year you are also asking for bill language to change the statutory allocation formula for distributing these funds to the States. In other words, that's what you are referring to in the sense that under the proposals, if they stay as they are, they would actually be out of step with what the law requires.

Ms. HARDY. Yes, sir.

DUPLICATION BETWEEN BLOCK GRANTS

Senator WEICKER. Earlier this week Secretary Heckler indicated that funding for the community services block grant should be combined with the social services block grant to eliminate duplication of services. What data has the Department collected from each of the States regarding the types of services provided under each block grant and the number of persons served in each program funded? For example, can you tell me how many day care centers are funded through the social services block grant in Connecticut and how many children are served? Also, how many centers are funded and children served under the community services block grant in 1982 and what is estimated for 1983?

Ms. HARDY. Under all of the block grants that we administer, and my primary responsibility is the social services block grant, we have not placed any reporting requirements on the States. We request a pre-expenditure report and a post-expenditure report.

It is our understanding from working with the States and talking with the State legislators that the States are spending most of the social services block grant dollars in a similar pattern as they spent under the title XX program. This would mean that the primary service for which funds are being spent is day care. In 1981, under the title XX program, approximately 20 percent of the money was spent on day care. We are confident that there still is approximately 20 percent being spent on day care under the social services block grant. We do not have the specifics as to exactly how many children are being served.

Senator WEICKER. Does that same hold true, I might add, for employment services or nutrition programs? You can't give me any breakdown of that?

Ms. HARDY. Not under the block grant, sir, no. We can under programs that are directly Federally administered.

Senator WEICKER. If you don't have that information, then how can we have generalized statements, as given by the Secretary, relative to overlap and duplication?

Ms. HARDY. Our previous experience indicates that separate Federal funding flows for similar activities tend to be accompanied by duplication and overlap at the State and local levels.

Senator WEICKER. What is the status of proposed legislation to ask the authorizing committees to combine these block grants?

Dr. VIETH. In answer to some of the questions that you have asked Ms. Hardy, we're asking that the community services block grant have no funding, that it be combined with the social services block grant, and that language be included to pick up the functions of the community services block grant.

We have done some evaluations. In fact we evaluate 10 States every year. We are finding with those evaluations and also with the National Association for State Community Services Programs that not only are the community action people being served, the poor people that are our clients, but also that services have been increased, have been expanded. I know there are a lot of counties and some towns and parishes that weren't covered by community action, and now that the States are addressing it they are taking that money and spreading it out so that more people are being served.

We also feel that the flexibility with the social services block grant will make it easier for them to focus and prioritize in different States and different counties so that they can serve these people. And that's why we are recommending no funding and just enough budget authority, about $2.8 million, to close out what we've already started in block grants and the discretionary activities.

Senator WEICKER. I don't know where you are getting your evaluations from. That's not the word I get from the State of Connecticut as to whether more are being served at this juncture.

Dr. VIETH. I have a letter from Ms. Beverly Gleeson. She is the president of the National Association for State Community Services Programs. They have checked the data. In fact we gave some money to three organizations to do some research and they are finding that the States are expanding coverage despite the sharp cutback in available funds. Some States now have 25 to 50 percent more of their areas served than were served by CSA grantees in the past. States are using more equitable formulas. States are making the CSBG program a vital part of the State safety net for closely related programs serving the poor.

They seem to be keying mostly on emergency assistance.

CSBG funds actually administered are close to $2.7 billion in total programs. So it shows that if we put in $360 million that they are picking up a lot of money from other programs, and States are beginning to get some innovative programs.

I think this shows that the decision the Congress made in the beginning was right, that the States can prioritize what they need to do.

If you are talking about a safety net, I think that the social services block is serving poor people, and if you add the language we are requesting they should be able to pick up and fill in where the needs are, whereas the categorical grants were just being funneled into specific areas many times that were not particular priorities to the States.

So I think that a combined block would be a good program, and that if you don't fund the community services block the combined block could pick up a lot of areas just because States will have a flexibility that they haven't had in the past.

Senator WEICKER. This is going to be $450 million less.

Dr. VIETH. In the program that I am managing it's going to come out to be $298 million less, and the Department is proposing to increase the social services block by $50 million. But basically, if you don't have the discretionary you're talking about $260 million.

Senator WEICKER. Social services is $2,675,000,000, community services $373,000,000, for a total of $3,048,000,000 for 1983. For 1984 social services block grant is $2,500,000,000, nothing for community services block grant, for a total of $2,500,000,000. That to me reads $548 million.

Dr. VIETH. I was speaking just of my program sir.

Senator WEICKER. So $500 million less, and what you are saying is we are going to serve more.

Dr. VIETH. I think it's very difficult for me to sit here and say if you cut $300 million that that money would be available. But on the other hand, I think the fact that States have the flexibility to focus this money will allow them to pick up areas that they couldn't before. Not only that, but the States themselves are putting money into the program. We found that to be true in Minnesota and North Carolina. These programs are just now coming in for evaluation.

Senator WEICKER. I'm not going to sit here and refute you. I don't have the facts in hand. I don't presume, as this budget presentation presumes, that more is going to be done with this much less. But I think probably what I would like to do is have some evaluation made of both what it is that is happening and what it is that is proposed. I will ask the committee staff in conjunction with the General Accounting Office to go ahead and prepare that study.

I have a feeling, with all the numbers being done on some people that are the weakest elements of this society in the name of some experimentation and theory, that that is not quite good enough.

The one thing I do have in front of me is this $500 million less. Maybe there are some savings to be achieved. That's a huge amount. Again I am speaking for the State of Connecticut, and I believe most

States. Two factors are present right now. No. 1, those that would normally be served are at record numbers because of the economic conditions in the country and the constituency has soared and most of the States are in pretty bad financial shape. I know my State of Connecticut certainly is, and I think there are others that share that condition.

Dr. VIETH. Senator, I went to Chicago and my one purpose was to go to the community action agencies and talk with them. The question I asked was if there was any reason for anybody in the city of Chicago to go hungry or to starve because they couldn't get any food, and the answer was "no," that they had enough food and they had ways of getting that food to people. Now it's true that somebody could starve if they didn't know. That's always a possibility.

So I think in some ways it's a priority. We are in difficult times, and faced with a $200 billion deficit, then I think the priority is the key.

I asked them, "If you were to get some money through the jobs bill"—this was when the jobs bill was just being discussed—"what are some areas that you would use that in?" The community action people said that they would hire people directly which would take care of the jobs situations, because if you give them $1 million, then they will hire so many people and that would certainly put people back to work.

And I said, "If you do that, do you have enough food and enough supplies so that these people would really have something to do?" And they said "yes."

But some of the priorities that they discussed, one of which—and I certainly don't speak against this, because I think it is nice to have except possibly in this day of limited money. They had a welcome baby program that they wanted to start, and I asked them how they could identify the poor babies in this program just strictly to help the people that we're trying to direct the money toward, and they said that they would be covering all people.

I know from my experience with community action that they do a good job, but possibly they have to redirect it so that you do take care of clothes, shelter, and food.

Senator WEICKER. I must confess when I hear that nobody is going to starve in Chicago and that's the basis on which we decide whether the programs are working or not—you've got to be kidding. Does that mean as long as somebody isn't going to starve in the United States everything is all right?

Dr. VIETH. From my experience as a county commissioner before I came here, I think that that is certainly a basis and a place to start. If you only have a limited amount of money it certainly should be directed. Because I think there could be areas where people do starve.

Senator WEICKER. I'm glad to see that we can at least use that as a starting point, that the administration doesn't want people to starve. What about all the services that are represented by this? It goes considerably beyond just food.

Senator Proxmire.

Senator PROXMIRE. Secretary Hardy, on page 51 of your justifications, in describing the child abuse and neglect State grant program you estimate that 1.1 million children are abused and neglected each year and that 5,000 die from abuse and neglect. With a budget request of $6.7 million you will be spending about $6.11 for each abused child.

In another portion of your justification you talk about "programs which provide direct services to vulnerable groups in the population." Well, if there was ever a vulnerable group, this is certainly it.

So could you give me some insight as to why you decided to ask for a budget increase to serve an additional 29,100 Head Start children but settled on a level budget in this area? I wonder about those priorities.

Ms. HARDY. There is a significant difference between the two programs, and I think they are both good programs. The child abuse and neglect program is not a direct service program, but rather, these funds act as a catalyst to assist States in their efforts in such areas as public awareness campaigns, establishing hot lines or parent self-help groups, and in the training of volunteers. In the child abuse and neglect program our level budget request of $6.7 million is a very small portion of what is spent in this country on child abuse and neglect. There are other dollars coming from the community, coming from the private sector, coming from other Federal programs that go toward trying to decrease and prevent child abuse and neglect.

Senator PROXMIRE. Could you give me some notion of the dimension of those resources, other than the Federal Government's $6.7 million?

Ms. HARDY. I can supply that to you.

Senator PROXMIRE. Are they 4 times as much, 5 times as much, 10 times as much, 100 times as much as the Federal payment?

Ms. HARDY. I would say it is at least 10 times as much and probably even higher than that. The voluntarism, the parents anonymous chapters, the parents united chapters, are all examples of the kinds of things that are going on throughout this country that support abused and neglected children.

The over $6.7 million that is included in this request are coordinating moneys. They are used by States to seed some of their programs in the communities. So they are not always direct service dollars. Child protective services moneys that come from the State and that come from the Federal Government are the primary sources for funds used for abused children.

On the prevention side there is almost $160 million in child welfare services in our budget which the majority of times goes to protect children who are or who are potentially child abuse cases.

Senator PROXMIRE. I would appreciate it if you could document for the record the amounts that go into the program.

Ms. HARDY. Yes, sir.

[The information follows:]

FEDERAL AND OTHER FUNDS ASSOCIATED WITH THE PREVENTION, DIAGNOSIS, AND TREATMENT OF CHILD ABUSE AND NEGLECT

Federal funds, from sources such as child welfare services, social services block grant, and foster care provisions of the Social Security Act, support child abuse and neglect prevention and treatment programs. They amount to over nine times as much as the Federal child abuse and neglect State grants program. We estimate that State and private resources focused on the problems of child abuse and neglect account for an additional amount equivalent to the total of Federal support. Thus, other sources of support amount to an estimated 18 times as much as the Federal child abuse and neglect State grants program. In addition to funds directly addressed to solving the problems of child abuse and neglect there are other Federal funds which support related activities particularly child protection. We do not have figures for the amount of funds from the social service block grant program which is used for child protection, but we estimate that it is, at a minimum, $300 million, an amount equivalent to the estimated level of support provided by the title XX program for this purpose. In addition, $300 million are used for foster care from titles IV-A and IV-E of the Social Security Act, and approximately $21 million for title IV-B funds are used for this purpose. We do not include unspecified portions of Head Start appropriations, support for child day care programs under the social services block grant program, runaway youth program funds and other programs, which have secondary benefits to preventing child maltreatment.

CHILD ABUSE BUDGET

Senator PROXMIRE. Your budget justifications for the Runaway and Homeless Youth Act state that 56 percent of the eligible parents receive services. How many parents and children are helped by your child abuse budget?

Ms. HARDY. I'd have to supply that to you. I don't have that figure.

[The information follows:]

NUMBER OF PARENTS AND CHILDREN HELPED BY THE CHILD ABUSE AND NEGLECT BUDGET

The child abuse and neglect program is a developmental, rather than a direct-service program, aimed at assisting the States to improve their child protective programs and start up new programs to prevent child maltreatment. It is, therefore, difficult to estimate the numbers of children and parents directly helped by the program. Through pilot projects delivering direct services, we estimate that as many as 75,000 children and parents are assisted each year. Through the program improvements designed and implemented under the program, however, there is the potential to provide more humane and effective protective services to the 849,000 families, representing approximately 1.3 million children, who are reported to State agencies for known or suspected incidents of child maltreatment.

CHILD ABUSE PROGRAM REGULATIONS

Senator PROXMIRE. In discussing your regulatory activities on page 40 of your justifications you indicate that a notice of proposed rulemaking for the child abuse program was published on May 27, 1980, and that publication of final regulations is expected in the second quarter of fiscal 1983. We are now in the third quarter of fiscal 1983. Have the final regulations been published?

Ms. HARDY. We don't seem to have that answer, Senator.

Senator PROXMIRE. Will you let us know, if you can, if they are not published, when you expect to have them published.

[The information follows:]

CHILD ABUSE AND NEGLECT REGULATIONS

The final child abuse and neglect regulations were published on January 26, 1983.

LENGTH OF TIME TO PRODUCE REGULATIONS

Senator PROXMIRE. Why has it taken some 3 years to produce regulations for this program?

Ms. HARDY. On the child abuse and neglect program?

Senator PROXMIRE. Yes.

Ms. HARDY. I do not have an answer for that. I'm sure that there were a lot of different points of view as to how the program should be regulated. Regulations development does take a long time in any program.

SOCIAL SERVICES BLOCK GRANT

Senator PROXMIRE. On page 2 of your justifications you show an unobligated social services block grant balance of $92.7 million being carried over into fiscal 1983. Am I correct in my understanding that after the current fiscal year you will no longer have the authority to carry over funds appropriated into this program because appropriation language makes the funds available for only 1 year?

Mr. MOTTOLA. That's correct.

Senator PROXMIRE. You seem to have consistently overestimated your ability to obligate social services block grant funds. Back in 1980 your office estimated only $3.5 million would remain unobligated at the end of fiscal year 1980. The actual unobligated balance was $252.8 million. In the next 2 years you estimated that there would be no unobligated balances, and you wound up not being able to obligate $152.4 million in fiscal 1981 and $92.7 million in fiscal 1982. Why has there been such difficulty in obligating these funds in the year that they were made available?

Mr. MOTTOLA. It is primarily because we had difficulty predicting exactly when the States would make their claims. As you know, the nature of the law has now changed. This will no longer be a problem. It is no longer necessary for us to estimate. But because of the way the budget process operated in the past, we were trying to predict what the States would claim in a given fiscal year significantly in advance of the States making those claims. And that was the basic reason for the inability to estimate accurately.

It is a very small percentage of inaccuracy, but nevertheless there was inaccuracy in the estimating.

Senator PROXMIRE. There was a big difference between the estimated and the actual unobligated balances.

HOME-DELIVERED MEALS

On page 70 of your justifications you indicate that you will maintain the same level of funding for congregate meals and home-delivered meals for the aging that you are currently providing.

A recent study by the Department's Inspector General found that with the unmet need for home-delivered meals increasing at a faster rate than the funding available, the competition for funds between home-delivered meal programs and congregate meals programs is increasing.

Doesn't this study indicate that it might be wise to provide a greater percentage of your funds to the home-delivered meal program rather than continuing the current ratio between the two programs?

Ms. HARDY. We do know that there continues to be a demand for home-delivered meals. We have given more money to the congregate because we could serve more people there. There were also other people besides the Federal Government in the home-delivered meal business, the private sector specifically.

Senator PROXMIRE. But those receiving home-delivered meals are the ones who in a sense might very well be in more difficulty. If nobody comes to their house to give them the meals they may be in greater jeopardy.

Ms. HARDY. Right. Last year we put into effect a 20-percent-transfer provision from the congregate to the home delivered. The States can transfer those moneys. They have been doing that. They have been making use of that transfer provision.

Senator PROXMIRE. Just from the standpoint of cost, too, they could end up in very expensive nursing homes if they can't get home-delivered meals.

Ms. HARDY. Yes; I think the States have been making use of that transfer and have been increasing their home-delivered meals.

COST OF MEALS

Senator PROXMIRE. On page 70 of your justifications you estimate that the cost of meals distributed under your nutrition services program will fall by between 6 and 9 cents per meal between 1983 and 1984. What is the basis for your estimate that the cost will drop? It seems to me to be optimistic.

Ms. HARDY. We think we have been quite successful this past year in increasing our productivity in terms of our meals using some ways in which we can better manage the programs.

Senator PROXMIRE. Do you make any assumptions about the impact of inflation on food prices?

Ms. HARDY. We've made an assumption of 6-percent inflation in food costs.

Senator PROXMIRE. Even assuming a 5-percent increase in food costs, you believe you'll be able to cut costs by 6 to 9 cents a meal?

Ms. HARDY. Yes.

We also have projected increased income, increased program contributions from people participating in the program, and that will assist us also in reducing the cost on the Federal side.

Senator PROXMIRE. What has happened to costs in the last 12 months? Has there been any indication that you've been making progress that you can document already and that you expect to continue?

Ms. HARDY. Well, we've had a significant increase in our program contributions nationwide over this last year.

Senator PROXMIRE. My question had to do with cost per meal.

Ms. HARDY. In terms of the cost per meal we don't have the final figures in for this 6-month period.

Senator PROXMIRE. Do you know if they have gone up or down?

Ms. HARDY. I would say they are pretty level.

Senator PROXMIRE. How about the last period for which you do have figures? Is the cost about the same?

Ms. HARDY. Yes.

EMPLOYMENT AND ECONOMIC DEVELOPMENT PROGRAM

Senator PROXMIRE. The justification narrative for your employment and economic development program says that funds will be used in part "to make grants to individuals, organizations or groups of older persons who initiate economic development enterprises which, after start-up support, will become stable ongoing businesses owned and operated by the older persons."

That's a nice goal, but is it practical and achievable at a time when business failures are at an all-time high and most economists expect the recovery to be fairly weak?

Ms. HARDY. I believe that by adding an economic development approach to this program as opposed to a standard jobs approach where a person simply gets paid to do a job on just above minimum wage—that we can provide a longer job opportunity for these individuals.

I have had conversations with local people from area agencies on aging and they have come up with some very good ideas. Such as in the Florida area where there is a shortage in low-cost housing. They feel there is a way in which you can use dollars from this program by having an area agency on aging invest $5,000 or $6,000 with an individual, working with the unions and their support, to prefabricate housing that would be of assistance in that kind of climate.

They also would like to set up a food co-op.

So they are the kinds of jobs that I don't see competing—you indicated the business failures—in terms of a large industry. They are jobs that I think can provide support for those individuals who can then also share in the profits of that small company.

DEVELOPMENTALLY DISABLED

Senator PROXMIRE. On page 84 of your justifications you list eight Federal programs that provide services to the developmentally disabled. One of the programs cited is comprehensive health planning. Isn't that

a program that the President has proposed to terminate next year? And if so, how will health planning for the disabled population be supported in the future?

Ms. HARDY. Those are the listings, sir, of the other Federal programs that provide moneys for the developmentally disabled. We have about $4.5 billion for the disabled population in this country which is Federal dollars.

Senator PROXMIRE. My question related to the comprehensive health planning program which the President proposes to terminate.

Ms. HARDY. I understand that that has been proposed in the past and will continue to be proposed for termination.

Senator PROXMIRE. Well, if the program is terminated how will health planning for the disabled population be supported?

Ms. HARDY. The administration sees health planning as a State issue, and a free market and competitive kind of issue that can be addressed at the local level.

Senator PROXMIRE. So there won't be any Federal health planning program for the disabled?

Ms. HARDY. No, sir. There will be no dollars for health planning from the Federal Government.

Senator PROXMIRE. In other words, the Federal Government just won't assume that responsibility in the future, is that right?

Ms. HARDY. Correct.

FOSTER CARE PROGRAM

Senator PROXMIRE. You are proposing to cap the foster care program in fiscal year 1984 at $440,170,000, an increase of $45,170,000 over the current budget. If the program were not capped how much would the States be entitled to?

Mr. ITTEILAG. Senator, we think that is the amount that the States will require in fiscal year 1984 irrespective of whether the cap proposal is enacted or not. In other words, the intent of the cap proposal was to primarily be effective in the year 1985 and subsequent years.

Senator PROXMIRE. I'm not sure I understand why you need a cap if you say that's what the cost would be anyway.

Mr. ITTEILAG. Senator, the proposal was primarily to have a cost restraining effect in years subsequent to fiscal year 1984, but we wanted to introduce the idea at this time to allow the Congress sufficient time to consider it.

Senator PROXMIRE. So the cap will extend beyond the fiscal year for which the funds are provided. Isn't that unusual?

Ms. HARDY. No; the permanent cap of $440 million would be part of our legislative proposal.

Senator PROXMIRE. After 1984?

Ms. HARDY. In 1984 and beyond.

Senator PROXMIRE. And beyond?

Ms. HARDY. Yes, sir.

Senator PROXMIRE. So that means that you propose that we put a limitation on future Congresses.

Ms. HARDY. That is what we are proposing.

I would like to point out what has been happening in the foster care area. Our recent figures show we have had almost a 14-percent decrease in the number of children in foster care over the last 2 years. We believe that with that decrease this $440 million is sufficient for future years, and we also believe that the foster care population will continue to decline.

Senator PROXMIRE. The costs of the program seem to be growing at a very, very rapid rate. Last year the cost was $2,674 per child. This fiscal year the cost is expected to increase to $3,745 per child and in fiscal year 1984 even with the cap the cost would be $4,683 per child. Those costs have gone up 75 percent in 2 years.

Ms. HARDY. I think those costs are too high, and I think with the decrease in the foster care population coming down that we should be able to not only have less children in foster care because they are either being adopted or they are not going into foster care, but we should also be able to reduce costs for those children who are in foster care. To have those costs go up so dramatically is a concern to me.

Senator PROXMIRE. Thank you, Mr. Chairman. I have some other questions for the record.

DAY CARE FOR LOW-INCOME FAMILIES

Senator WEICKER. Thank you very much, Senator Proxmire.

If funding for day care projects for low-income families currently provided by the community services block grant is zeroed out as you propose, what likelihood is there that these projects would be continued under the social services block grant where you are also recommending less money than is currently available?

Ms. HARDY. We estimate that about 20 percent of all of the social services block grant moneys throughout the country are used for day care and I anticipate that the States will still use those dollars for that service and that the people who are using community services day care would be eligible from the combined block grants.

Senator WEICKER. Dr. Vieth, what is the amount allocated in the area of day care?

Dr. VIETH. It's not specified, so we don't know. We don't have that figure.

HEAD START TRAINING AND STAFF DEVELOPMENT CUTBACK

Senator WEICKER. Head Start faces a rather high degree of staff turnover. I notice that you are planning to expand services by over 29,000 children in fiscal 1984, and yet you propose a 50-percent reduction in training, staff development, technical assistance, research, and evaluation. How do you justify such a significant training and staff development cutback during a time of program expansion?

Ms. HARDY. We are decreasing approximately $11 million of the Head Start training and technical assistance and redirecting that to direct classroom funding. We believe that the remaining $13.4 million will be sufficient to provide training and technical assistance for those staff that are there. I think we are seeing that we have had turnover in the Head Start program in the past. I think some of that will continue, but I also think there is a lot of stability with many of the people who are in the Head Start program.

SPECIAL HANDICAPPED PROJECTS

Senator WEICKER. How can you cut funding for special handicapped projects in half, from $2.4 million down to $1.2 million, and still assure that local Head Start projects get adequate help to deal with the special needs of handicapped children?

Ms. HARDY. We think that the resource access projects, which are one of the primary areas funded out of those dollars, are important, and we have maintained those and we feel that they are doing a very good job in getting to the local levels.

We are also putting some assistance through some of our other programs like the university affiliated facilities working with Head Start programs, day care programs, whatever, in the local community. We think there are other resources to train many of those teachers.

Senator WEICKER. 39,600 currently make up approximately 10 percent of handicapped children in the Head Start enrollment and this will increase in 1984 to 42,500.

Ms. HARDY. At least that, yes.

Senator WEICKER. Yet the funding goes from $2.4 million to $1.2 million.

Ms. HARDY. The $1.2 million support only training, technical assistance, and access activities. Those dollars are not service dollars for those children.

Senator WEICKER. I understand that. What goes to those children is the expertise of the people that handle those children.

Ms. HARDY. Right.

Senator WEICKER. You're halving that budget while at the same time your clientele is on the increase; you're halving that budget which I think both of us would agree in the area of special education is crucial.

Ms. HARDY. We're trying to integrate the whole handicapped program within Head Start, and I think we have sufficient dollars throughout Head Start and throughout other programs that are funded at the local or the State level for assisting with these children.

MEALS FOR HEAD START CHILDREN

Senator WEICKER. You are proposing a direct appropriation of $76 million into Head Start in fiscal 1984 to cover nutritious meals for the children. This would replace the existing system whereby Head Start projects were reimbursed $76 million in fiscal 1984 by the Agriculture Department's child care food program. I'm not prepared to go ahead

and say whether the committee is going to support the transfer. But how are you going to feed 29,000 more children in fiscal 1984 with the same amount of money transferred from the Agriculture Department's child care food program?

Ms. HARDY. The Department of Agriculture dollars provide about 60 percent of the total food and food service costs in Head Start and about 40 percent of that money comes from the overall Head Start appropriation. So there is built into our Head Start request sufficient dollars, we believe, for feeding the children that are currently enrolled, and the new children. We estimate that we would have approximately $2.50 a day per child per day. About 14 percent of our Head Start children are in full-day programs, which would mean that for most of the children we are providing less than three meals a day.

We believe that there are sufficient dollars available to feed all of the Head Start children.

Senator WEICKER. Maybe I've missed your answer. I still don't understand how 29,000 more children are going to be fed with the same amount of dollars.

Ms. HARDY. Because nutrition dollars are already built into the $62 million increase that we are asking for in Head Start.

Senator WEICKER. The current cost per child is $193 in 1983. Now it's going to decline under the appropriation request to $180, a cut of 7 percent in actual dollars. With inflation at 5 percent that would be a real cut per child of 12 percent.

Mr. MOTTOLA. Mr. Chairman, when the budget was constructed we built the total amount for nutrition for the increased number of children into the increased request. We recognize that the Agriculture money was to cover only the children in the Head Start base for this fiscal year, and we did recognize that there was additional money required for that purpose, for the new children to be served, and that is in the requested amount of $62 million.

Senator WEICKER. Counsel tells me the budget doesn't indicate that; maybe you ought to file an amendment to your budgetary presentation.

CLOSURE OF OCS REGIONAL OFFICES

At the end of March 1983 you closed down the regional offices of the Office of Community Services. transferring staff to other regional office components of the Department of Health and Human Services.

What provisions have been made to insure adequate Federal monitoring and technical assistance with respect to community services block grant activities?

Dr. VIETH. The only purpose of the regions were closeouts of CSA grants. At no time were they doing any technical assistance. All technical assistance was being done by headquarters staff. Not only that, but last year we gave some funding to the National Governors Association so that they could provide technical assistance and do research to find out where the problems were. We are in daily contact with the States for whatever problems they have.

We could not justify keeping the regions open because some of them only had about 4 hours of work for a whole week. Not only that, we closed out 1,500 grantees and we have about 70 to go. It all had to do with waiting for the audit to come in and we're handling that at headquarters. So what we have done now is detailed most of those people in the regions to HHS and some to other departments.

What we are trying to do is develop some permanent jobs. There is no guarantee now. We are trying to develop permanent jobs so that we can possibly get by without having a RIF on October 1.

CHILD WELFARE SERVICES PROGRAM

Senator WEICKER. In spite of reports of escalating numbers of abused and neglected children and increasing demands on child welfare and social services systems around the country you've again proposed level funding of $156.3 million for the child welfare services program. At the same time you are recommending the child welfare training program be consolidated with the services program, but no funding for training be added. How do you justify what amounts to a reduction in child welfare services funding at this time?

Ms. HARDY. The $156 million budget request is not the total picture of what is going on in the States in terms of child protective services. There are other dollars the States can add, if they choose, out of other programs, out of the social services block grant, and other areas. That's the State's decision, and we requested level funding for that reason.

HOME-DELIVERED MEALS FOR THE ELDERLY

Senator WEICKER. Your budget proposes an 8-percent reduction in Federal funding for home-delivered and congregate meals for the elderly, yet you project no reduction in the number of meals to be provided in fiscal 1984. How can you realistically continue to serve the same number of meals when you propose to cut Federal funding by $32 million?

Ms. HARDY. We believe that we can serve the same number of meals through our productivity increases that we have put into place, and through increased program contributions, and we have mapped out a strategy with the area agencies on aging, and with the State units on aging for doing this. I believe that we can do this. We have been successful by serving more meals than we were expected to have served in the past.

Senator WEICKER. How do you arrive at the estimate that the average cost per home-delivered meal will decline from $2.27 in fiscal 1983 to $2.18 in fiscal 1984 despite the impact of inflation?

COST OF HOME-DELIVERED MEALS

Ms. HARDY. We have done a lot of looking at the meals costs, and we feel that they can be decreased. I can provide for the record some of our background material and some of our data that we have been using.

I would also point out that local organizations do have a 20-percent transfer; if they want to transfer moneys from the congregate meals to home-delivered meals, they can also do that.

RESEARCH AND TRAINING FOR THE ELDERLY

Senator WEICKER. What is the rationale for now proposing a cut of $17,175,000, a 75-percent reduction in 1 year, from research, training, and special projects for the aging? I would note that this comes on top of a 45-percent cut in fiscal year 1982.

Ms. HARDY. That suggested decrease is consistent with our philosophy to decrease the budget. We should take the dollars from nondirect services, especially the discretionary area.

Senator WEICKER. Well, my comment there is that the elderly population continues to grow rapidly in this country. I think the Nation is ill prepared as it is to accommodate to that particular phenomenon, and I just don't understand how at this juncture these types of cuts are in order.

[CLERK'S NOTE.—The letter from Ms. Beverly Gleeson referred to on page 419 will be inserted in the record at this point.]

LETTER FROM BEVERLY J. GLEESON, MINNESOTA CHAIRPERSON, NATIONAL ASSOCIATION FOR STATE COMMUNITY SERVICES PROGRAMS

FEBRUARY 23, 1983.

Senator PETE V. DOMENICI,
Chairman, Senate Budget Committee,
2317 Dirksen Senate Office Building, Washington, D.C.

DEAR SENATOR DOMENICI: The staff of the Senate Budget Committee has asked this office to provide you with information on how the 50 States and the territories have administered the community services block grant program since October 1, 1981, when the Congress set in motion the transition from Federal to State administration of this antipoverty program.

We are pleased to provide this information, and look forward to working with the committee and its staff to develop any other facts and data you may desire.

As you know, Congress terminated the Community Services Administration October 1, 1981. CSA had had an appropriation level of $524 million for fiscal year 1981. It distributed about $375 million in so-called local initiative funds to about 900 community based organizations in fiscal year 1981. It was essentially this portion of the CSA program which was continued as the community services block grant, at a program level of about $348 million for both fiscal years 1982 and 1983.

Jointly with the National Governors' Association, this association has received a grant from the Office of Community Services (OCS) in the Department of Health and Human Services to provide technical assistance to the States in this program. This project is the principal source of factual data on the CSBG program.

We have several comprehensive surveys underway. WE are conducting a series of training wrokshops, and are developing a unique data base on the State-administered programs, as shown in the attached report.

It is important to emphasize that the community services block grant program is not really a "State" program.

Congress has directed that the funds be used "to ameliorate the causes of poverty in communities within the State."

Furthermore, Congress has required that States pass-through 90 percent of their allocations to community based organizations previously funded by CSA—primarily the 900 "community action agencies" (CAA's) or similar "limited purpose agencies" (LPA's), or rural migrant or farmworker groups.

These local grantees provide a variety of services and special activities as determined by their own boards of directors, who must represent the poor, local officials, and the civic leadership of the community.

So, the CSBG funds which Congress makes available to States are being passed-through to community boards which are delivering services and sponsoring activiites which they believe are most effective in dealing with poverty in their communities. States do recognize that they are now accountable for how these funds are used, something they were not accountable for in the past.

A major challenge facing the States involves this question of accountability: namely, how does the State make the critical judgments necessary to set program priorities and maintain management control of the program, while at the same time complying with the congressional mandate that the funds be passed-through to local boards to finance locally designed programs. This is a major topic for our training and technical assistance project.

Special interest seems to center on the changes which have occurred as a result of the congressionally-initiated shift to State administration of the program as a block grant.

These are the key changes which we identify:

States are expanding the coverage of the program to counties which were not served when the program was administered by the Federal Community Services Administration, despite a sharp cutback in the available funds. (Some States have had 25 to 50 percent or more of their areas unserved by CSA grantees in the past.)

States are using more equitable formulas in distributing funds within the State. (CSA apparently had no specific formula for allocations within States; some CSA grantees received grants many times larger than other grantees serving similar populations.)

States are making their CSBG program a vital part of the State safety net of closely related programs serving the poor and disadvantaged. for example, our survey indicates that more than one-fifth of the total CSBG allocation is being used at the community level to provide emergency assistance. The local grantees which the States are funding with some $315 million a year in CSBG funds actually administer close to $2.7 billion in total programs—private, local, State, or federally funded. It is important to understand this fact—that the CSBG program does not stand alone but becomes a core unit within a State and local network of programs.

States are beginning to innovate as to program design and content—even though Congress has sharply restricted the funding to specific "eligible entities" previously funded by CSA. For example, some States are making job creation and economic development a priority for their grantees. Some are using the 5 percent of the State allocation not earmarked by Congress as a special fund for innovative approaches to fighting poverty. Some are developing "score cards" for grading local grantee programs, and rewarding outstanding programs with extra funds.

Your budget committee staff raised several specific questions:

1. Have all States taken over the CSBG block grant?

   Yes; 35 States took over the program at the first opportunity, on October 1, 1981. The rest assumed responsibility at various dates during fiscal year 1982. Effective October 1, 1982, all States took over the program. OCS is no longer making grants to CSS's or monitoring such grants.

2. What specific things does the program do?

   The program provides continued funding to a network of community based organizations which, under general State supervision, provide services in areas such as employment assistance, special education, housing assistance, consumer counselling, emergency assistance, food and nutrition programs, encouraging low income persons to participate in community institutions, developing linkages with other programs for the poor, and so forth.

3. Have the States improved on the administration of the program?

We believe that they have, and we are gathering examples to illustrate this point. For example, some States have greatly improved monitoring of the program, appointing special citizens commitees to review the programs of local grantees, and following up with regular on-site assessments by State evaluation teams. Some States have insisted that delegate agency boards become more personally involved in their agency programs, and not just leave them to the paid staff. Many States are integrating the CSBG program with the Low Income Energy Assistance, Weatherization, and/or Job Training Partnership Act programs to provide more comprehensive assistance and to reduce administrative costs. States are requiring much more accountability for their CSBG grants; many States insist that these funds be treated as program funds with a specified limit allowed for administrative costs.

Finally, questions have been raised as to whether there are any particular problems in CSBG administration to date.

The overriding problem involves the uncertainty and irregularity of funding. As you know, the principal argument made for block grants was that States should be in a better position than a Federal agency in Washington (or a Federal regional office) to design and administer a program which dealt with problems which were of a State and local nature—such as the problems of poverty. However, for this concept to work, a State must know what kind of funding it is going to receive, and when the funds can be expected.

Ever since the CSBG authorizing legislation was enacted in July 1981, the States have had to live with great uncertainty over the funding levels and the date when funds could be expected. The funding recommendations have ranged from zero to $389 million (the authorized level). The program was initiated in fiscal year 1982 at the $225 million level, then later expanded to the $348 million level, then later cut back to allow for a Secretary's discretionary fund which was not a part of the administering agency's original plans.

In most of fiscal 1982 and 1983, grants have been awarded for only one quarter at a time, and generally as much as 6 weeks after the quarter has begun.

Obviously, extreme administrative difficulties are created for States in administering a program—at Federal direction—without knowing the amount of money to expect, nor when it will be received. States are required by law to pass-through funds to local agencies; yet agencies which have staffs to maintain, and services to provide, have no way of continuing their programs when the funds are not provided. Many States are forbidden by law to advance money in such situations, and almost all of them are in fiscal situations which make this financially, even if not legally, impossible.

Another problem relates to the administrative expenses for small States. While the 5 percent administrative expense is adequate for many States (and some indeed don't use it all but instead pass it along to communities), States receiving $1 million or less are barely able to afford more than a single staff person. This makes it virtually impossible to carry out the State functions mandated in the act, such as processing grant applications, monitoring grantees, and providing the specific "assurances" required in the act.

In conclusion, we wish to emphasize that the community services block grant program is a uniquely congressional program. It was developed as a compromise within the Senate Committee on Labor and Human Resources, passed by the Senate, and accepted by the House as a part of the Omnibus Reconciliaton Act of 1981. Even though States did not develop the proposal, they have welcomed the program, have accepted responsibility for it, and are making a concerted effort to administer it as effectively and efficiently as possible. The States look forward to congressional oversight hearings on the program.

Please let me know if there is further information we can provide to your committee.

Sincerely,

BEVERLY J. GLEESON,
Minnesota chairperson, NASCSP.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. I have other questions which will be submitted for response to the record, as do other Senators.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

Questions Submitted by the Subcommittee

TITLE XX "MAINTENANCE OF EFFORT"

Question: Would you favor retaining a " maintenance of effort" proviso in the Fiscal 1984 Social Services Block Grant Legislation?

Answer: No. We would not favor a "maintenance of effort" proviso in the FY 84 Social Services Block Grant legislation. We are convinced that States should continue to have the flexibility that the original legislation intended and that they have used to continue meeting the needs they know best. The trend toward transferring funds from other block grants into the Social Services Block Grant continues and indicates that where additional funds are needed for services, States meet the need by using other Federal as well as State resources.

Question: Now that States are no longer required to furnish a non-federal share to receive Title XX funds, to what extent are State, local, or private funds now available for social services programs?

Answer: While we do not have exact figures for each State showing the amounts of State, local or private funds available for social services programs, we know that some State and local funds have been utilized and in some instances increased in an effort to maintain or increase financial participation in these programs.

Based on a study in six States, we know that, for example, in FY 1982, Kentucky, New York and Oregon all made use of State General Fund dollars in their social services programs. In addition, New York developed a program of shared expenses with local governments, i.e., certain high priority services, particularly those addressed to children (excluding child day care) could be transferred to a program paid for half by the State and half by county governments.

Question: What level of effort have the States maintained under the block grant in spite of the fact that a match is no longer required?

Answer: Data on State funding and expenditures are not required to be included in the States' pre-expenditure reports.

Therefore, at the present time we do not have the precise figures for each State to answer this question.

ENACTED SUPPLEMENTALS - THE "JOBS BILL"

Question: How soon will these funds be distributed to the States?

Answer: The funds will be distributed to States as soon as we receive the required assurance from each State that the funds will be spent "in addition to rather than in lieu of other State and Federal funds for these purposes." We estimate that all the assurances will be received by mid-May.

Question: What is your estimate of how much of these resources States can actually spend by September 30, 1983?

Answer: We estimate that 75 percent of the funds will be spent by September 30, 1983. The bill and supporting reports make it clear, that the supplemental funds are to be expended as expeditiously as possible.

USE OF SOCIAL SERVICES BLOCK GRANT FUNDS

Question: How has the removal of targeting requirements affected the type of person being served?

Answer: The information available in the State Social Services Block Grant pre-expenditure reports does not indicate that the removal of the targeting requirements has significantly affected the types of persons being served. All States continue to offer services to AFDC and SSI recipients and other low-income persons.

Question: Has there been any shift in types of services being provided?

Answer: There have been some shifts in the types of services being provided, but we believe most States are providing essentially the same services under the Social Services Block Grant (SSBG) in FY 1983 as in FY 1982. For example, in FY 1982, 51 States used SSBG funds to provide day care for children. In FY 1983, 48 States used SSBG funds for this service. At least one State that had previously used SSBG funds is still providing child day care but is funding it from other sources. In the adult services area, 17 States used SSBG funds to provide foster care for adults in FY 1982, while 24 States indicated they would use SSBG funds to provide this service in FY 1983.

Question: Has the block grant resulted in the reduction of administrative costs?

Answer: As States are not required to report this information, we do not have a specific answer to this question.

The GAO report, "Early Observations of Block Grant Implementation", found that some States noted some savings associated with reduced application and reporting procedures. It also found that most States had not departed significantly from Federal fiscal and administrative standards due to the short time frame for block grant implementation and, in part, because of a reluctance to have two sets of standards for Federal programs.

In addition, we have anecdotal information that shows some States have made organizational and administrative changes to accommodate the block grants, e.g,. centralization and consolidation of similar programs. We expect that States will make more changes as they build experience in administering block grants.

Question: How are States' activities in regard to the Social Services Block Grant being monitored?

Answer: The block grant legislation and regulations place great reliance on State oversight processes. The primary oversight vehicle contemplated by the block grant legislation is the State audit. Therefore, for monitoring purposes, the Department will rely on the States' pre-expenditure reports, biennial reports and audits.

In addition, we will review any GAO audits; investigate and resolve any complaints relating to State administration on the SSBG, including complaints of discrimination; and utilize reviews by the Inspector General to prevent fraud and abuse and promote efficiency and economy.

IMPACT OF 1981 LEGISLATION ON TITLE XX SOCIAL SERVICES

Question: Now that the Social Services Block Grant has been fully in effect for one fiscal year, what do you know about the impact on the legislative changes in the Reconcilation Act of 1981 on State social services programs?

Answer: The Omnibus Budget Reconcilation Act of 1981 removed many requirements and provided greater flexibility to States in administering social services programs. However, we have noted some basic similarities with the previous program.

For example, despite the absence of requirements: (1) the evidence shows that States continue to involve their citizens in planning Social Services Block Grant (SSBG) expenditures through public hearings, providing opportunities for comments on proposed use reports and through greater involvement of State legislatures; (2) public assistance recipients such as SSI and AFDC recipients continue to be served in all States; and (3) as reflected in State pre-expenditure reports for FY 82 and FY 83, there are no dramatic changes in the range of services provided by States.

Question: For example, now that States are completely free to set their own income eligibility guidelines and are not required to serve specific groups, such as welfare recipients, how does the population served differ from that under the old law?

Answer: A review of the States' FY 1982 pre-expenditure reports and a sample of FY 1983 reports indicates that all States have continued to make services available to the poor, i.e., public assistance recipients and other low income persons. Eligibility requirements appear to have been tightened so that the poor and near poor may well represent a greater proportion of the population receiving services.

TITLE XX TRANSFER OF FUNDS

Question: To what extent are States transferring Social Services Block Grant funds for use under the Health or Energy Assistance Block Grants and vice-versa?

Answer: In FY 1982, twenty-six States transferred funds from the Low-Income Home Energy Assistance (LIHEA) block grant program to the Social Services block grant (SSBG) program.

Only one State transferred SSBG funds to another block grant, i.e., to the Alcohol, Drug Abuse and Mental Health Services program.

Information on transfers in FY 1983 is still being collected. However, we do know that 23 States have transferred or are planning to transfer funds from the LIHEA block grant to the SSBG program.

Question: Would you advocate a change in the Title XX legislation, changing the program from an entitlement to an appropriated program?

Answer: We are not proposing such a change.

Question: Would you prefer more discretion in submitting budget requests for this program than is allowed by the appropriated entitlement?

Answer: As noted in the previous question, we are not requesting that the appropriated entitlement feature be changed.

IMPACT OF SOCIAL SERVICES BUDGET CUTS

Question: For specific population groups, such as the elderly, handicapped children or welfare recipients, what have been the combined effects of legislative changes in Title XX and Federal budget cuts?

Answer: Most States did not include in their pre-expenditure reports information regarding the level of funding or number of individuals who would receive specific services. We are therefore unable to assess the impact on specific population groups at this time. However, we know that SSI recipients, which include the elderly and handicapped children, and AFDC recipients continue to be served.

Question: What has been the impact of budget reductions in "Title XX" social services on States?

Answer: At this time, we do not have sufficient data to determine the impact of budget reductions. However, we know that some services being provided by States are not provided Statewide; States are increasing the use of fees based on income; and States are tightening eligibility requirements so that welfare recipients and the near poor appear to be the recipients of most services. We have also noted that some services previously funded under the Social Services Block Grant have been transferred to other funding sources.

Question: In States which are eliminating or consolidating services to save money what types of services are being dropped?

Answer: We cannot state why States eliminated or consolidated services. Our analysis of the FY 1983 pre-expenditure reports show that services eliminated or consolidated from Title XX funding varied from State to State. In some States where services were eliminated under the SSBG, they were transferred to other programs, e.g., in one State "day care" was transferred to Title IV-A, and in several other

States "in-home services" (homemaker, home-health aide, chore, respite care) were transferred to Title XIX.

Question: Among States serving fewer recipients, are income eligibility guidelines being lowered so that fewer people are eligible?

Answer: In the FY 1983 SSBG pre-expenditure reports most States did not indicate the number of individuals served. However, we know that some States have tightened their eligibility guidelines for particular services and therefore, fewer individuals are eligibile for service.

Question: Are any States eliminating group eligibility determinations for the elderly?

Answer: Many of the States which included group eligibility in the FY 1983 pre-expenditure reports did not specify to what groups the group eligibility applied (i.e., children or elderly). Therefore, we are unable to determine if States are eliminating group eligibility determinations for the elderly.

REPORTING REQUIREMENTS UNDER SOCIAL SERVICES BLOCK GRANT

Question: Are there sufficient reporting and auditing requirements in the Social Services Block Grant legislation to provide the Federal Government with timely and accurate information on how Federal funds are being spent?

Answer: The biennial State reports and audits of the Social Services Block Grants are due to be received by the Department in FY 84. We believe these materials, together with the pre-expenditure reports we have received for FY 82 and FY 83, will give us a good picture of how block grant funds have been spent to provide social services as intended by the legislation. State audits must be conducted by independent entities and in accordance with generally accepted auditing principles. For these reasons, we believe that the audits will give us an accurate picture of how Federal funds are spent and the adequacy of State financial management controls.

Question: Do you agree with a recent conclusion of the General Accounting Office that national assessments of the Social Services Block Grant and other new block grant programs will be seriously hampered by the lack of standard block grant report formats or uniform data collection at the Federal level?

Answer: No. Given that the responsibility for the management of the resources rests with the States, we do not believe that standard reporting formats are essential to carrying out our responsibilities. We believe State pre-expenditure and post-expenditure reports and the voluntary State reports will provide the necessary information for Federal purposes on how Federal funds are being spent.

Question: Will the data you are now collecting on the Social Services Block Grant be adequate for making national policy decisions?

Answer: Yes, we believe the various sources of data we are utilizing will provide adequate information for making national policy decisions.

One of the intended benefits of the block grant legislation was to reduce State reporting to information which is essential to Federal administration and Congressional oversight.

Therefore, we plan to utilize available information, e.g., statutorily-required reports; information available from Federal staff, documents and records; non-Departmental studies by such organizations as the General Accounting Office and the Advisory Commission on Intergovernmental Relations; studies and reports produced by non-Federal organizations such as the National Governors Association; voluntary uniform State data being collected by the American Public Welfare Association; and limited studies by the Department.

SOCIAL SERVICES TRAINING

Question: Now that training is no longer a separately authorized activity under Title XX, to what extent are States using their Block Grant funds to provide training to State and local social services personnel?

Answer: We do not have specific data on this area, but in examining State pre-expenditure reports we note a trend toward reducing administrative costs and increased use of volunteers. Therefore, our general impression is that training of staff has been reduced under the Social Servies Block Grant.

HEAD START INCREASES

Question: The total increase for local Head Start projects is $80.2 million. Of this amount, $42.1 million will be targeted to innovative projects. Is it your intent to distribute the entire increase of $80.2 million on the basis of the formula?

Answer: Of the $80.2 million increase to local projects, $16.1 million is projected to meet higher operating costs. The balance, $64.1 million, will be distributed according to the formula and traditional Head Start practices in using the Secretary's discretionary reserve to fund increases in Indian and Migrant projects, and in the Territories.

Question: If not, how will the $42.1 million be targeted?

Answer: It is estimated that $42.1 million, roughly two-thirds of the the $64.1 million available for expansion, will be targeted to innovative projects. It is possible that even more of that amount will go to innovative projects since innovative design is expected to be an important criterion for awarding new money.

Question: When you speak of "innovative projects", what do you mean?

Answer: Innovative projects include Employment Based Head Start programs to enable parents to receive job training, and collaborative ventures with agencies that are presently providing some services to preschool children, including private non-profit child care providers. Also contemplated are Head Start satellites which could link Head Start centers to satellite homes in which small groups of children could be served; and services for children with special needs, such as Native American children, refugee children, or other vulnerable minority groups.

HEAD START RESEARCH AND DEVELOPMENT

Question: Over the years, Head Start research and development funds have spurred innovative ways of meeting the changing needs of children and families. Among other things, Head Start has helped develop the concept of the parent as the primary teacher of the child. The entire child development community has benefited from this and other ideas. In light of the contributions Head Start's research and development funds have made possible, how do you justify cutting these funds?

Answer: Head Start is a mature program which has amply demonstrated its effectiveness. As with most mature programs the number of research and development issues requiring investigation has diminished. Rather than spending the previous high levels of research and demonstration funds on redundant and low priority research, we are seeking to redirect a portion of these funds to enhance program operations directly benefiting Head Start beneficiaries.

The amount proposed in the budget is adequate for the Head Start research and demonstration priorities for Fiscal Year 1984. Head Start research and demonstration efforts for Fiscal Year 1984 will emphasize dissemination and utilization of findings so that the Head Start experience can benefit all our nation's children. Other efforts will be directed toward maintaining and further improving the quality of the Head Start program and finding ways to deliver services in a more cost effective manner.

HEAD START COMPETITIVE BIDDING

Question: We understand that you plan to depart from the traditional grant process and allocate the expansion funds by a competitive bidding process to existing and new Head Start grantees. How do you plan to allocate the expansion funds beyond what is required by the Head Start funding formula?

Answer: Funds for Fiscal Year 1984 expansion will be distributed to the States by the legislative formula, and to other jurisdictions by allocating discretionary funds to Indian Programs, Migrant Programs, and Territories. The formula combined with allocations from the Secretary's discretionary funds will determine the expansion funds for each jurisdiction.

Question: How will you assure that funds will go to communities with the greatest unmet need?

Answer: Finer distributions of funds, within States and Territories, will be controlled by selection criteria which are

expected to include: cost-per-child; relative need in the area to be served; capacity of the applicant; extent to which the design shows innovation and appropriateness to the target population; and extent to which the applicant can meet Head Start standards.

Competition is the method traditionally used by Head Start to award replacement grants in communities where the original grantee has been defunded or has relinquished the grant. Under no scenario for competition presently being contemplated would any existing local Head Start program not be eligible to apply for expansion funds.

QUALITY OF HEAD START SERVICES

Question: In past hearings concern has been expressed by the Committee about three indicators of Head Start program quality: staff salaries, teacher/child ratio, and the number of pupils per classroom. What are the latest statistics on these three areas?

Answer: Staff salaries at the local grantee level have risen substantially in recent years. The average teacher salary which in Fiscal Year 1980 was approximately $6,900 rose in Fiscal Year 1981 by 12 percent to $7,728 and in Fiscal Year 1982 by 12.6 percent to $8,700.

The ratio of classroom staff to children has also improved in recent years. Figures for Fiscal Year 1980 are flawed, showing a staff/child ratio of 10.3 to 1. The ratio was probably not that high, but the figures for Fiscal Years 1981 and 1982, which have around one staff member for every eight children, are clearly an improvement. The staff/child ratio is expected to hold constant at 8:1 in Fiscal Year 1983 as well.

Class size also shows an improvement. In Fiscal Year 1980 average class size was 20.4, in Fiscal Year 1981 18.6, and in Fiscal Year 1982 it had been reduced to 18.2 children in a classroom on the average.

Question: What will be the affect of the flat funding level on Head Start from fiscal 1982 to fiscal 1983 on these three areas?

Answer: Data for Fiscal Year 1983 will not be available until next fall, but the flat funding from Fiscal Year 1982 to Fiscal Year 1983 is not expected to affect adversely any of these indicators. Head Start programs traditionally have found a way to maintain any advances which they or which they and the Government together have achieved. Anecdotal information indicates that grantees are maintaining these new levels.

Question: How much of the proposed fiscal 1984 funding increase will be devoted to improvements in these areas?

Answer: The proposed Fiscal Year 1984 Head Start budget provides for $16.1 million to be devoted to meeting higher operating costs, some of which would otherwise have squeezed class size and child/staff ratios. In addition, applicants for new Fiscal Year 1984 funds will be judged partially on the basis of the cost-effectiveness of their applications and the attractiveness of the designs they propose. These criteria will

encourage applicants to propose satisfactory levels in all three of these indicators. The exact amounts will be determined by the interaction between ACYF Regional Offices and the applicants themselves.

REDUCING HEAD START PER CHILD COSTS

Question: What is the status of the effort now going on to reduce per child costs in high cost Head Start Grantees?

Answer: ACYF has begun to implement the Head Start Cost Management Project which examines, through the use of a cost analysis instrument, the cost per child and the cost per hour of Head Start services in relationship to program structure and program quality. Areas in which funds are not being efficiently used are identified and adjustments are made in the kind of services being provided, the amount of services being provided and the number of children being served. In the latter two instances, cost per year and cost per hour are reduced. To date, 110 grantee budgets have been identified for review and results should be available sometime during the summer.

Question: What factors contribute the most to high cost per child rates in local Head Start Programs?

Answer: The most costly expense that Head Start incurs is the cost of staff which makes up approximately 75 percent of program budgets. The factors leading to high personnel rates on a per child basis are the hours of service provided to each child and the number of children in each classroom. As the number of hours of service increases, the costs per hour for each child falls. As the number of children in each class increases, the cost per hour of service also falls.

In addition, factors affecting cost also include the structure of the program being implemented, staffing patterns and staff employment by week and year, the ratio of classroom to non-classroom staff and the size of the program.

Question: How can these factors be controlled?

Answer: We are beginning to identify some grantees in which cost savings can be instituted and are in the process of developing systems that utilize the cost management system as an analytic tool to review grantee budgets to make sure that Head Start funds are being used as effectively and efficiently as possible. In addition, we intend to explore some policy issues and concerns that directly affect cost to see if cost savings can be instituted on a policy basis without adversely affecting program quality or the local program's decision-making authority.

Question: What safeguards are there to ensure that program quality does not suffer when per child costs are cut in local Head Start Programs?

Answer: The cost analysis sytem presently being implemented is a method of making judgments related to the costs of individual grantees. The quality of the programs is protected by several safeguards: the cost analysis instrument is designed to ask cost

questions in relation both to the way the program is structured (the program option being implemented) and the quality of the program being implemented; the system allows for the reasonableness of costs to be determined on a grantee by grantee basis; and the decisions related to budget changes in the name of efficiency are made by Federal staff in conjunction with grantee staff.

CUTS IN HEAD START-RELATED PROGRAMS

Question: Please describe the impact of cuts and changes in the following programs on local Head Start programs, from Fiscal Year 1981 to Fiscal Year 1982, and from Fiscal Year 1982 to Fiscal Year 1983: public service jobs, child nutrition programs, social services block grant, community services block grant, and Medicaid.

Answer: These funding sources were either eliminated or reduced which resulted in a loss to Head Start of approximately $34.9 million in value.

Question: Very specifically, what has been the impact of these changes and cutbacks on Head Start programs?

Answer: Comprehensive Employment Training Act supported Head Start workers in Fiscal Year 1980 numbering approximately 4,600, most of whom held positions as teachers, teacher aides, and clerk-typists. The salary support was valued at $26.9 million.

Title XX supplemented over 200 projects and was projected to total $12.1 million for FY 1982. With a reduction of 25 percent in Title XX supplements, Head Start estimated its loss at $3 million.

The Community Services Administration provided administrative support to Head Start through Community Action Agency grantees. The pressure for Head Start to pay indirect costs increased with the award of negotiated indirect cost rates. Approximately $5 million of the existing Head Start budget was used to pay these rates for the administration of Head Start programs.

Since October 1982 several states have made changes in their Medicaid/EPSDT programs. The impact of these changes has been to reduce the number of Head Start children eligible for Medicaid/EPSDT health services. The two significant Medicaid/EPSDT program changes have been the reduction in eligibility categories and changes in EPSDT periodicity schedules.

Several states have removed the medically needy and other categories for EPSDT eligibility. This has the effect of reducing preventive health care services to families who would have no other means available to pay for these services.

For example, the State of Idaho has revised its periodicity schedule. The new schedule does not include EPSDT services for children ages three through five . EPSDT medical and dental services are no longer available to the Medicaid eligible Head Start children in the State.

Question: What have Head Start programs done to make up for these losses?

Answer: Head Start has always had as part of its mission the mobilization of community resources to aid in carrying out program objectives in order not to rely entirely on Federal funding. Head Start programs drew from volunteer resources, linked into the block grant resources in their States or counties and changed hours of operation in order to reduce salary costs without affecting program quality. In a few cases they changed the program mode, for example, from full day to part day, or from center-based to home-based. In the case of Medicaid/EPSDT, Head Start will have to forge additional linkages in support of medical and dental health services for Medicaid eligible children. A major EPSDT linkage effort is under way in several ACYF regions. Part of the effort involves developing regional and State level EPSDT taskforces, and developing Head Start - EPSDT interagency agreements in States where these do not exist.

Question: What guidance have you given local programs in finding alternative sources for lost services and in-kind support?

Answer: Since Head Start programs have extensive and long-term experience with mobilizing resources no specific guidance was given as to where alternative sources might be found. However, Head Start has begun its cost study which resulted in a cost analysis instrument. By Fiscal Year 1984 all regions will have been trained in the use of this instrument which will assist them in the most economic use of funds for an efficient quality program.

Question: Have you determined what impact your Fiscal Year 1984 proposals in these areas may have on Head Start?

Answer: No determination has been made of the impact of other Fiscal Year 1984 proposals on Head Start. The Fiscal Year 1984 Head Start budget is proposed as a program and fiscal package which will succeed on its own and in concert with other Administration proposals for Fiscal Year 1984.

HEAD START SET-ASIDE

Question: Please describe the allocation of Head Start's 13 percent set-aside in Fiscal Year 1983 and the proposed allocation in Fiscal Year 1984.

Answer: The 13 percent set aside, which in Fiscal Year 1983 amounted to $118.6 million, was allocated by first directing $15.1 million to local Head Start projects in addition to the $793.4 million provided by the formula. The balance was distributed in the categories provided by statute: $65.1 million to Indian and Migrant programs; $4.1 million for the Virgin Islands and the Outer Pacific; $25 million for training and technical assistance; $2.4 million for special handicapped projects; and $6.9 million for research, demonstration, and evaluation.

For Fiscal Year 1984, in a budget of $1,050,650,000, we estimate that the 13 percent reserve would be distributed as follows: $77 million for Indian and Migrant programs; $13.4 million for training and technical assistance; $1.2 million for special handicapped projects; $1.8 million for research, demonstration, and evaluation; and the balance of $43.2 million will be allocated to

local Head Start projects in the States and the Virgin Islands and the Outer Pacific.

Question: Please provide for the record a detailed description of how Head Start research and demonstration funds were spent in Fiscal Year 1982.

Answer: For Fiscal Year 1982 the amount budgeted for research and development in Head Start was $9.6 million. Of this amount, $1.9 million was funded to Head Start's Child and Family Resource Programs; $2.5 million was distributed by the Regions to assist in the conversion of summer-only Head Start programs and to increase Head Start enrollment on a one-time basis; $.7 million was managed for Head Start by the office of the Assistant Secretary for Planning and Evaluation for Head Start-related evaluation; and approximately $4.5 million was devoted to research and demonstration projects awarded through the Human Development Services Discretionary Funds Projects. Some of these Human Development Services projects involve supplemental funding from Human Development Services agencies outside of Head Start. Their work covers a wide range of activities including linkages with other community service providers, and use of volunteers.

Question: What has been the effect on Head Start of having research and demonstration projects administered as part of a larger Office of Human Development Services discretionary funds program?

Answer: The improved approach to awarding and managing research and demonstration projects has enabled Head Start to benefit in a number of ways. It has been possible in some cases to pool Head Start funds with those of other programs to make more cost effective awards and to produce equal results with a lower cost to both programs. It has also enabled Head Start to take advantage of the expertise of others in the Office of Human Development Services in planning and managing research and demonstration projects.

Question: What safeguards are there to ensure that all Head Start research and demonstration funds are spent on Head Start-related projects?

Answer: When the Office of Human Development Services' research and demonstration projects are announced in the Federal Register, the program sources of funding such as the Administration on Aging, Head Start, Youth Bureau, are identified, along with the dollar amount available from that program source for each Research and Demonstration priority. Applicants are thereby alerted at the beginning of the process. Then as meritorious proposals are considered, the Administration for Children, Youth and Families matches proposals against its Research and Demonstration priorities, as do other Human Development Services agencies, and the Commissioner of Administration for Children, Youth and Families meets with other Commissioners to be certain that each agency's budget and Research and Demonstration commitments are met at the same time that they are maximizing their buying power by jointly funding some projects.

HEAD START

Question: What was the total Head Start enrollment in Fiscal Year 1982 broken down by full-year, summer, Parent Child, Indian, and migrant?

Answer: By the end of Fiscal Year 1982 Head Start enrollment in full year projects equalled 395,800 children. Of these, 4,300 were in Parent and Child Centers, 13,500 were in projects serving Indian Reservations and 17,250 in projects serving the children of migrant farmworkers. The process of converting Summer Head Start projects was virtually completed in Fiscal Year 1982. Only 70 children remained in Summer projects..

Question: What are your projections of the enrollment in Fiscal Year 1983 and Fiscal Year 1984?

Answer: Head Start enrollment for Fiscal Year 1983 is projected at 395,800 and in Fiscal Year 1984 enrollment is projected at 424,900. There will be no summer enrollment in these years.

Question: Are there plans to use any funding increase in Fiscal Year 1984 to increase Head Start enrollment? If so, how will you ensure that program quality remains as high as before? If not, for what purpose will such increases be used?

Answer: Funding increases in the amount of $64.1 million in Fiscal Year 1984 will be used to increase Head Start enrollment by 29,100 children. Program quality will be maintained by providing adequate funding for the increased enrollment, and by awarding these funds under criteria that place a premium on the ability to meet Head Start standards.

HEAD START COST OF LIVING

Question: Looking at the funding for Head Start programs for next year, what allowances are you making for cost-of-living increases in their budgets?

Answer: The Fiscal Year 1984 budget reserves $16.1 million to maintain program quality related to higher operating costs in non-personnel areas that cannot be overcome by improved productivity. This would average 6.4 percent of the non-personnel portion of the budget in every Head Start program.

HEAD START AND CHILD CARE

Question: The Conferees on the recently enacted "jobs" supplemental included report language urging that "Day care services be assigned a high priority by the States and local communities in planning the use of the additional funds provided in this bill". What are you doing to give priority emphasis to day care services, not just in Fiscal Year 1983, but in Fiscal Year 1984 as well?

Answer: The special child care needs of those who are seeking work or are in job training programs are recognized by

most local Head Start programs, which make the choices among the eligible population in their communities. To encourage special consideration of these needs, Head Start is planning in Fiscal Year 1983 to direct some of the increased funds going to some states by virtue of an increase in the poverty population toward employment based Head Start services or agencies which will link Head Start services with existing day care providers. For Fiscal Year 1984 examples of the innovative funding approaches to which expansion funds will be directed include employment-based Head Start and collaborative ventures with existing non-profit child care providers.

Question: Since most Head Start projects are only half-day programs, aren't the full-time day care services available under the Social Services Block Grant better suited to the needs of low-income families?

Answer: Children of low income working parents need comprehensive developmental services for learning, health and socio-emotional growth as well as full-time child care during the period their parents work. There are approximately 349 Head Start programs that provide some full-day services, or roughly 19 percent of all Head Start programs, to respond to both aspects of the child's and parents' needs. Many Head Start programs utilize Title XX funds from the Social Services Block Grant for supplemental child care to complement a part-day Head Start program. A total of 223 Head Start programs receive some Title XX support.

In Fiscal Year 1984, the Department is planning to assist Head Start programs in their efforts to cooperate with day care providers to serve low income working parents more effectively. In addition, a national study was launched in Fiscal Year 1983 to analyze Head Start eligibility, outreach and recruitment and to determine the extent to which children in various types of families are being served. As a result of this study, it will be possible to identify further opportunities for community level coordination between Head Start and day care.

Both Head Start and day care services under the Social Services Block Grant are vital parts of an overall pattern of child care services for low income families.

HEAD START TRAINING AND TECHNICAL ASSISTANCE

Question: Please describe briefly the changes you have made last Fiscal Year relating to the provision of training and technical assistance to Head Start Grantees.

Answer: In Fiscal Year 1982, the delivery of Head Start training and technical assistance services was further decentralized by reducing the amount of funds previously programmed at Headquarters level and allotting a larger share of available training and technical assistance resources for programming at the Administration for Children, Youth and Families regional office level. Restructuring of training and technical assistance delivery systems was accomplished in eight regions and a portion of the Indian and Migrant Programs Division, resulting in the establishment of a network of primarily State-wide training and technical assistance grantees. Each training and technical

assistance grantee was required to have an advisory group comprised of representatives from Head Start programs and Head Start associations located in the State as well as other persons representing the broad child care community.

In addition to funding these State-wide training and technical assistance providers, approximately 25 percent of the total available training and technical assistance funds was given directly to Head Start programs having the capability to manage and secure their own training and technical assistance services.

Question: What is the status of these changes?

Answer: The State-wide training and technical assistance grantees in the eight regions and Indian and Migrant Programs Division are in place. Preliminary reports indicate that Head Start programs are receiving the training and technical assistance they have requested to meet their needs. For the most part, regional offices and the Indian and Migrant Programs Division have decided to obligate Fiscal Year 1983 funds for continued support of their current training and technical assistance delivery systems.

Question: Are there indications yet that these changes have resulted in more effective training and technical assistance and/or saving money?

Answer: We will complete an assessment of the impact of these changes in July 1983. At that time we expect to have reached conclusions pertaining to the quality of training and technical assistance provided under the current system and cost savings derived as a result of changes made. Preliminary reports, however, indicate that some savings are being realized through the participation of non Head Start resources and utilization of currently employed Head Start grantee staff as trainers and technical assistance experts.

HEAD START VOLUNTEERS

Question: How many paid staff and how many volunteers were there in Head Start programs in fiscal 1982? In Fiscal Year 1983? How many do you project for Fiscal Year 1984?

Answer: In Fiscal Year 1982 there were an estimated 73,170 paid staff and 494,300 volunteers. In Fiscal Year 1983 we estimate 74,300 paid staff and 500,300 volunteers. The projection for Fiscal Year 1984 is 79,800 paid staff and 537,100 volunteers.

Question: Has the ratio of paid staff to volunteers in Head Start programs been changing? If so, how?

Answer: The ratio has held constant in recent years, despite increased competition for volunteers in most communities.

Question: What is the optimum level of volunteer use in Head Start programs?

Answer: While Head Start does not specify an optimum level, there is a limit to the number of volunteers that can be

used due to the need for supervision of volunteers by paid staff. Moreover, some skills needed in Head Start are not generally available as "volunteers", for example, doctors, social workers and psychologists.

Question: Is there a trend toward fewer people volunteering in local Head Start programs? If so, what can be done about it?

Answer: No, the number of people volunteering has increased in absolute numbers.

Question: To what extent have volunteer programs under ACTION been tapped as a resource for Head Start volunteers?

Answer: Administration for Children, Youth and Families has a formal inter-agency agreement for placing Foster Grandparents and Retired Senior Volunteer Program volunteers in Head Start programs.

Question: How many Head Start volunteers are parents of Head Start children? Has this number been increasing or decreasing?

Answer: For every three children enrolled, at least two Head Start parents are providing a volunteer service. The number has been increasing.

Question: How many Head Start parents received Child Development Associate Certificates through Head Start in FY 1982? How many received paid jobs?

Answer: Of the total 2,600 Child Development Associate persons credentialled in Fiscal Year 1982, 70 percent were Head Start staff. While t[illegible] Child Development Associate credentialling agency has never been requested to break out or identify the number of Head Start staff that are parents, we estimate that approximately 30 percent of the Head Start staff credentialled were parents. Thus in Fiscal Year 1982 an estimated 550 of those credentialled were Head Start parents, together with an unknown number of non-Head Start staff some of whom would also be current or former Head Start parents.

Question: How many Head Start parents received paid jobs?

Answer: Head Start projects reported that, during the 1981-1982 school year, 28.7 percent of their paid staff, or an estimated 21,300 persons, are parents of current or former Head Start enrollees.

HEAD START

Question: What is the average salary for a Head Start teacher in a unionized school system?

Answer: No figures are available on teacher salaries in this category.

Question: In a nonunion program?

Answer: No figures are available on teacher salaries in this category.

Question: In urban programs?

Answer: No figures are available on teacher salaries in this category.

Question: In rural programs?

Answer: No figures are available on teacher salaries in this category.

Question: Are there plans to a use funding increase to equalize these differences?

Answer: There are no plans to use any funding increase to equalize salaries.

Question: Please tell us the number of full year Head Start programs, the number of summer programs, of Indian and Migrant programs, and the number of Parent Child Centers in Fiscal Years 1982, 1983, and projected for 1984.

Answer: The number of summer programs has declined from prior years, as the phase-out progresses. In Fiscal Year 1982 one summer program was funded. In Fiscal Year 1983 and Fiscal Year 1984 no summer programs will be funded. The numbers of Indian programs 93, Migrant programs 24, and Parent Child Centers 36 are expected to remain fairly constant over the three years. The number of full-year Head Start programs exclusive of those mentioned above, was 1,108 in Fiscal Year 1982, is also expected to be constant for Fiscal Year 1983. Fiscal Year 1984 expansion will bring a number of new grantees into the Head Start system, including possibly some new Indian grantees. All will be full year programs. Since the emphasis is on increasing enrollment through innovative approaches in Fiscal Year 1984, no estimates are available of the number of grantees that will be added, that will be a function of the marketplace.

Question: When will the phaseout of the Head Start summer programs be completed?

Answer: The phaseout of summer Head Start programs will be completed in Fiscal Year 1983.

Question: How many summer Head Start programs have been converted to regular programs, and how many were phased out entirely?

Answer: According to available information only one summer-only Head Start program was phased out entirely. The other 64 were converted to full year Head Start, some of them by combining with other summer programs, others by combining with full year programs in the same community. The conversion was facilitated by the addition of $463,000 to help some summer projects convert to full-year.

Question: In those summer Head Start programs converted to full year programs, where has the additional required funding come from?

Answer: Summer Head Start programs which converted to full year either converted within their own budget by reducing enrollment and increasing the level and duration of services or combined with other summer programs to form a single full year project, or received additional funds from Regional Offices to enable them to convert.

Question: Have the Parent Child Centers been converted to regular Head Start programs?

Answer: Parent Child Centers have not been converted to regular Head Start programs.

HEAD START REGULATIONS

Question: What is the Administration's official position on revising Head Start Regulations?

Answer: The Administration's position is that there will be no major revision of Head Start regulations. We have informed local Head Start programs of this decision.

Question: What feedback have you been getting from the Head Start Community concerning your plan to revise Head Start regulations?

Answer: The Head Start community strongly opposed the revision of Head Start regulations. Their main point was that the Head Start program has been operating well under the existing regulations. The regulations set high program and administrative standards. Therefore, they see no reason to revise the regulations.

Question: Do you currently have plans for making any major changes in Head Start operations, such as were proposed in your October 1981 strategy paper?

Answer: We do not plan to make major changes in Head Start operations such as those proposed in the October 1981 Strategy Paper.

CHILD WELFARE RESEARCH AND DEMONSTRATION

Question: Please describe the projects funded under the Child Welfare Research and Demonstration program in Fiscal Year 1982. In Fiscal Year 1982, did Child Welfare Research and Demonstration funds go toward any jointly funded projects under the Office of Human Development Services Discretionary Funds Program?

Answer: In Fiscal Year 1982 Child Welfare Research and Demonstration Program funds supported 18 projects which were jointly funded with funds from other Human Development Services program funds.

Question: If so, what were these projects?

Answer: The projects which received joint funding came from a number of the priority areas described in the Fiscal Year 1982 Announcement of the Human Development Services Coordinated Discretionary Programs. The priority areas included: assisting State and local governments in reviewing and modifying standards and licensing practices; work measurement studies of service providers; family centered preventive social services modalities; protection from abuse and neglect in residential settings; coordination of protective services and legal judicial system; Regional Resource Centers on Children and Youth Services; employer based family support; and alternative public initiatives.

Question: For the record please list these projects and show which discretionary programs their funding came from.

Answer: The projects receiving joint funding support and the source of their funding is as follows. The following abbreviations are used in the table: ADD - Administration on Developmental Disabilities Special Projects; AoA - Administration on Aging Research and Demonstration; HS - Head Start Research and Demonstration; ANA - Administration for Native Americans Research and Demonstration; CAN - Child Abuse and Neglect Discretionary funds; AO - Adoption Opportunities Programs; 426 - Child Welfare Research and Demonstration; SSR - Social Services Research and Demonstration.

Project and Funding Sources

American Bar Association	426, AoA, ADD
California Department of Developmental Services	426, ADD
University of Maryland Center for Productivity	426, HS
National Coalition for Hispanic Mental Health and Human Services Organization	426, AoA
Temple University	426, ADD
National American Indian Court Judges Association	426, ANA
Judge Baker Guidance Center	426, CAN, AO
Cornell University	426, CAN, AO
Virginia Commonwealth University	426, CAN, AO
University of Tennessee	426, CAN, AO
University of Wisconsin at Milwaukee	426, CAN, AO
University of Texas at Austin	426, CAN, AO

University of Iowa	426, CAN, AO
University of Denver	426, CAN, AO
California State University at Los Angeles	426, CAN, AO
University of Washington	426, CAN, AO
Child Care Association of Dallas	426, HS
Foundation for Human Services	426, HS
Community College of Greater New York	426, SSR

Question: What types of projects will be funded in Fiscal Year 1983 and Fiscal Year 1984?

Answer: In Fiscal Year 1983 Child Welfare Research and Demonstration funds will be used to support projects in 10 of the 14 priority areas announced for the Human Development Services Coordinated Discretionary Funds Program. Since the applications for all funds under that program are now under review, it is not possible to describe the specific projects which will be supported with child welfare research and demonstration funds either jointly with other program funds or entirely by these funds. The priority areas in which Child Welfare Research and Demonstration funds will be used include: Employment and Income Generation; Community and Family-based Care; Targeting Resources; Prevention and Early Intervention; Adoption and Foster Care Opportunities; Improved Use of Management Information Systems; Program Management Improvement; Evaluation Assistance, Training; and Dissemination and Utilization.

HEAD START AND DAY CARE

Question: What is the number of children currently served by Title XX day care?

Answer: The most recent information on this is contained in the Summary Report of the Assessment of Current Practices in Title XX - Funded Day Care Programs submitted to the Congress in October, 1981. Based on the data in that report we estimate that about 500,000 children are currently served by Title XX day care programs.

Question: With increasing emphasis by the Administration on "workfare," -- and, hence, need for day care -- should we be thinking about introducing some of the concepts that have made Head Start so successful into day care?

Answer: While there are differences between the basic program goals of Head Start and day care there are a number of facets of the Head Start program which have already had some impact on day care. States have adopted the Child Development Associate concept, originated by Head Start, into their day care licensing laws. The importance of the parent as the primary educator of the child and as being involved with the direction and management of child care programs is becoming more common among day care programs. Many day care providers use Head Start generated materials in their

programs. The Federal role in day care is to make available concepts, ideas and best practices to States, local governments and day care providers who can choose the kinds of programs and activities which best fit their particular needs.

FOSTER CARE

Question: Are all States receiving Federal reimbursement for Foster Care Maintenance Payments under Title IV-E of the Social Security Act?

Answer: All States except Massachusetts are currently receiving reimbursement for foster care maintence payments. The Massachusetts Title IV-E State Plan was only approved on February 8, 1983. It is effective beginning in Fiscal Year 1983. The State has not yet requested reimbursement for the Federal share of their Title IV-E Foster Care expenditures.

Question: How does the Department of Health and Human Services know that States are eligible for the funds?

Answer: Each State has submitted a Title IV-E State Plan, which has been reviewed for compliance with the Act and approved by the Regional Program Director for Children, Youth and Families. States report actual expenditures for funds spent after the end of the quarter. These reports are reviewed by the Regional Office of Human Development staff to ensure that only allowable expenditures are reimbursed.

CHILD WELFARE TECHNICAL ASSISTANCE

Question: What is the Children's Bureau plan for providing technical assistance to the States regarding the implementation of major reforms as required by the Adoption Assistance and Child Welfare Act of 1980?

Answer: There are several ways in which the Children's Bureau is providing assistance. Children's Bureau provide consultation, information, referrals and other assistance by telephone or in person, to States and program level officials. In addition, the Children's Bureau awards grants which assist States in meeting the requirements of the law. One major effort has been to fund the National Center on Family Based Services, School of Social Work, University of Iowa, to provide technical assistance and consultation to States to assist in the implementation of preplacement preventive services. The Center will identify and describe exemplary programs, help States to assess their current needs and to develop policy, planning and program as needed, and develop handbooks for State administrators and others resources as appropriate. The Center has provided direct assistance to eight States, and more limited consultation to many others. A National Dissemination Conference is scheduled for May, 1983. Current information indicates that States are most limited in their capacity to provide preventive services to minority families. An Fiscal Year 1984 initiative will provide service improvement grants to those agencies wishing to provide more appropriate services to their minority families. A current

effort is being carried out by the National Child Welfare Training Center.

The aim of the Center is to enhance the capacities of State and local agencies and social workers to provide child welfare services that meet the pressing needs of families and children. Through the Regional Centers on Children, Youth and Families, training and technical assistance is provided to States, as requested in their attempts to meet the requirements of the law in such areas as case management, recruitment and training, revising policies and standards, working with the courts, etc.

CHILD WELFARE PROGRAM REVIEWS

Question: It has come to the Subcommittee's attention that the Department does not intend to continue the child welfare program reviews that it had been conducting jointly with the States on a voluntary basis for the past two years? Yet it is our understanding that many of the 28 States in which reviews have been conducted have found these reviews to be very useful in assessing their programs and services. On what basis did the Department come to the decision to terminate the reviews?

Answer: OMB clearance for the manual used in these reviews had expired in December, 1982. We intend to revise and streamline the manual in conjunction with the States and disseminate the revised manual for voluntary use by the States.

FOSTER CARE GOALS

Question: Have all the States succeeded in setting goals establishing the maximum number of children in Foster Care for more than 2 years, as required by the Adoption Assistance and Child Welfare Act of 1980?

Answer: All States have met this requirement.

Question: If so, what are they? If not, what is the delay?

Answer: States could establish goals either as percentages or as absolute numbers. Forty-two States used percentages which ranged from 1 percent reduction of case load per year, 7 States, to 50-80 percent reductions, 9 States, in the first year. The absolute numbers included the numbers by which the foster care case load in States, 10 States would be reduced. California expressed its goals both as a number and a percentage.

Question: Do you think these goals are realistic?

Answer: The States seem to be in three categories in establishing their goals. The first category are those States which have aimed high, set their goals as something to be striven for, but realize they might not be attained, 21 States with goals of 30 percent reduction or more. The second category includes those that have mounted strenuous efforts to reduce the number of children in foster care and have set goals that they feel they can realistically achieve, 11 States with goals between 6 percent and

29 percent. The third category are those States which may be doing good work, but because of their concern about non-achievement of goals have established goals which they are certain they can achieve, 19 States with goals of 5 percent reduction or less.

Question: To what extent do these goals vary from State to State?

Answer: Goals have been established at both extremes. In at least four States the goal is not to reduce the number of children in care more than 24 months, but to keep the caseload from exceeding a certain number, equal to or greater than the number presently in care more than 24 months. The other extreme is represented by Vermont which proposed an 80 percent reduction and Kansas which proposed to have no children left in care more than 24 months.

FOSTER CARE PREVENTIVE AND REUNIFICATION SERVICES

Question: Do you expect that all the States will succeed in providing preventive and reunification services for each foster child by the end of Fiscal Year 1983, as required by the Adoption Assistance and Child Welfare Act?

Answer: In Fiscal Year 1982, 44 States had certified their eligibility for funding from section 427. Of these, 12 had certified only for section 427(a)--reunification services, and 32 had certified for both 427(a) and (b)--preplacement preventive services. Additional States have certified in Fiscal Year 1983, leading us to believe that by October 1, 1983, all of the States and jurisdictions will have programs to provide preventive and reunification services to children and families. As such programs are requirements for States to receive payments under Title IV-E after October 31, 1983, there is strong incentive to develop and implement them by that date.

Question: How many States are in compliance with this goal now?

Answer: The Regional Offices are in the process of verifying State's certifications for section 427 funding. At the end of Fiscal Year 1982, 29 States had been approved for additional funding and nine decisions were pending.

Question: In those States that are now in compliance, what have been the effects of providing these services?

Answer: Research findings are not available at this time to correlate the provision of preventive and reunification services to reductions in the foster care population.

INSTITUTIONAL FOSTER CARE

Question: Last year the Committee expressed concern about the number of children in institutional care. What are the most

recent figures on the number of children in institutional foster care?

Answer: The 1977 National Study of Social Services to Children and Their Families reported that 78,292 children were in institutional foster care under the supervision of State child welfare agencies. This constituted 20 percent of the total foster care population at that time. Recent information from two States Illinios and Virginia, suggests that this percentage may have declined to 12-13 percent. Data for Fiscal Year 1983 is currently being collected. Information from this survey will be available in July.

Question: How much does institutional foster care cost in relation to foster family care?

Answer: Examination of board rates for foster family care and for institutional foster care in Maryland and New York reveals that institutional foster care may cost from three to six times more than foster family care. There is wide variation because foster family board rates vary with age and other factors in most States from $1,200 - $5,500 per year. Costs for some facilities are as high as $45,000 per year for emotionally disturbed children in residential treatment.

Question: What are the States doing to deemphasize institutional foster care?

Answer: Deinstitutionalization is extremely varied from State to State. For example the number of institution beds per 10,000 youth varies from a low of 10 per 10,000 population to a high of 39, based upon preliminary findings of a research study by the University of Chicago. Recent institution population shifts include a growing number of institution serving mental health and juvenile justice populations, the most expensive types. The institutional population however has remained fairly constant for 15 years. In Fiscal Year 1981 it was 172,939, excluding treatment facilities for emotionally disturbed children and facilities for handicapped children. The number of institutions has doubled, to a total of 4,814. This is a reflection of one aspect of deinstitutionalization, that is, development of smaller institutions, which sometimes are referred to as community based facilities or group homes. There are many specific activities occurring to deemphasize institutional care, this includes preventive services; greater attention to criteria for removal; greater attention to criteria for selective placement; greater use of alternative resources, e.g. relative day care, day treatment, specialized family foster care; greater attention to case planning, positive involvement with families, provision of after-care services, and; greater emphasis upon adoption when parents and relatives are unable or unwilling to provide care.

Question: What help is the Federal Government giving States in deemphasizing institutional foster care and stressing family foster care?

Answer: The most intense and continuing help probably is given by the Office of Juvenile Justice, Department of Justice which made deinstitutionalization a condition of funding to the States. Most of the permanency planning activities and materials of the Children's Bureau have served to carry this further by reducing inappropriate institutionalization in the first place. Technical assistance to the States and materials developed by the Children's Bureau in the areas of residential care and licensing of child placement and child care also have emphasized specific activities to reduce inappropriate institutional care.

FOSTER CARE EXPENDITURES RECORD

Question: What were total Federal expenditures in the foster care program in Fiscal Year 1982?

Answer: States filed claims of approximately $352 million as the Federal share of the Title IV-E or IV-A-Foster Care Program expenditures for Fiscal Year 1982.

Question: What were total State expenditures in Fiscal Year 1982?

Answer: The total State share claimed of Fiscal Year 1982 foster care expenditures is approximately $300 million.

Question: What are projected State and Federal expenditures for foster care for Fiscal Year 1984?

Answer: We estimate State and Federal foster care expenditures for Fiscal Year 1984 will be approximately $800 million, of which $440 million will be Federal.

FOSTER CARE STATISTICS

Question: Please give us the latest annual statistics in the following areas: number of children in foster care, number of foster children legally free for adoption, number of children placed for adoption, number of foster children returned to their own homes. What are the most current annual statistics on children in foster care? What are the projections for Fiscal Year 1983 and Fiscal Year 1984?

Answer: Foster care statistics were collected from nine large States for December 31, 1982. These nine States reported 113,554 children in foster care. In Fiscal Year 1980, the Office of Civil Rights, Department of Health and Human Services, collected data from all counties in the United States. The Office of Civil Rights study reported that there were 302,000 children in foster care in January, 1980. The Child Welfare League of America analyzed statistical reports from 47 States for Fiscal Year 1980 and reported that there were 257,000 children in foster care in those 47 States. The 1977 National Study of Social Services to Children and Their Families, a sample survey of child welfare case records, reported there were 502,000 children in foster care. The Office of Human Development Services projects that in Fiscal Year

1983 there are 357,000 children in foster care and that in Fiscal Year 1984 there will be 336,000 children in foster care. We are conducting a sample survey of 206 county child welfare agencies to determine the number of children in foster care. Data from this survey will be available in July, 1983. In addition, the States, under the auspices of the American Public Welfare Association, are implementing the Voluntary Cooperative Information System which will provide data on the number of children in foster care by June, 1983.

The 1977 Study of Social Services to Children and Their Families reported that 100,000 children were legally free for adoption or 20 percent of the foster care population. The projection for the number of children legally free for adoption in Fiscal Year 1983 is 43,000 and for Fiscal Year 1984 is 50,000.

The 1977 Study of Social Services to Children and Their Families reported that 50,000 children were receiving adoption services. The projection for Fiscal Year 1983 is 27,000 and for Fiscal Year 1984 is 32,000.

The Office of Human Development Services estimated that in Fiscal Year 1980, 103,000 children in foster care returned to their own homes. The projection for Fiscal Year 1983 is 68,000 and the projection for Fiscal Year 1984 is 76,000.

The current survey and the Voluntary Cooperative Information System will provide current data.

Question: Have the States shown improvements in keeping fewer children in foster care and instead either placing them for adoption or providing services to enable them to return to their own homes?

Answer: Examination of trends from selected States reveals that the number of children in foster care has been declining at a rate of from between 4 percent and 6 percent per year. This decline is due to a number of factors such as increased use of preplacement preventive services, increased use of reunification services, increased adoption, increased case planning, stronger case review procedures, other general program improvements, and a decline in the child population.

RUNAWAY YOUTH

Question: The request for the Runaway Youth Program is $10,514,000, a cut of 51 percent from the $21,900,000 appropriated in 1983. The justifications says that the cut is in response to the "President's policy of reducing domestic spending where possible without damaging the programs which provide direct services to vulnerable groups in the population". It's one thing to say you won't damage the programs, it's quite another to cut services to homeless and runaway youth and their families. With this cut of 51 percent, how many youth will receive shelter and how many families and youth will be served through the hotline?

Answer: At the current time, it is anticipated that an appropriation of $10.5 million would be utilized to support approximately 170 community-based programs providing temporary

shelter and long-term counseling to an estimated 45,000 youth and drop-in services to approximately 135,000 young persons.

Additionally, the National Communications System, National Runaway Switchboard, would be funded at an approximate level of $350,000. This toll-free hotline would continue to provide referral and crisis intervention services to an estimated total of 300,000 youth and their families during Fiscal Year 1984. Based upon the results of its current effort to evaluate the operations and technical adequacy of the National Communications System, funding for the Switchboard would also be used to strengthen its technical capacity to more adequately provide information and referral services to an increased number of clients.

NUMBER OF RUNAWAYS

Question: Your budget indicates there are an estimated 733,000 to 1.3 million youth who either run away or are pushed out of their houses every year. Is the number of youth running away from home increasing?

Answer: The Office of Human Development Services' data on youth who receive services from the centers indicate an increase of approximately 25 percent in the number of these youth. A particularly dramatic increase has occurred in the number of young persons who are described as homeless by these centers.

Since the Department estimates that only about six percent of the total runaway and homeless youth population is served by these centers and that no national, regional, or State data are collected on the incidence of this phenomenon, it is difficult to unequivocably state that the overall dimensions of this problem are increasing.

Question: What can be done to prevent youth from leaving home?

Answer: The prevention of runaway behavior and the critical problems associated with this act for many youth, including increased health risks, vulnerability to sexual exploitation, and the absence of parental care and emotional support, are of considerable concern to the Department. Prevention of this problem, moreover, requires the identification and amelioration of family crises which may lead to runaway behavior or result in homelessness.

Various approaches can be and have been utilized in attempting to reduce or prevent runaway behavior. These efforts include the following areas of activity: active outreach program by both runaway centers as well as other youth-serving agencies and organizations to provide preventive counseling and related services to youth and families prior to a runaway episode; increased community education and public awareness initiatives by runaway centers, such as, training seminars for other community service agencies, professional service providers, and institutions, including schools, to identify, refer, and provide preventive services to youth and their families prior to a runaway episode or other family crisis; the support of networking initiatives at the State level to improve the ability of runaway service providers to

reach at-risk youth; and the support of the National Runaway Switchboard, which provides information and referral services to youth and families prior to as well as during family crises.

The Office of Human Development Services has also supported research and demonstration projects designed to identify and respond to critical youth issues on both a preventive as well as an ameliorative basis. These initiatives, which have addressed such problems as adolescent maltreatment, juvenile sexual exploitation, and the impact of parental separation, divorce, and remarriage on youth, have resulted in resource materials such as program development manuals designed to strengthen youth-serving programs in preventing or reducing the adverse impact of these problems.

Question: What is the role of the Runaway Youth Program in preventing youth from leaving home, as opposed to funding shelters for youth who have already left?

Answer: There are several components of the National Runaway Youth Program which address preventing youth from leaving home. The toll-free National Communications System plays a major role in addressing the problems of potential runaways. In Fiscal Year 1982, more than one-fourth of all calls were from youth who were contemplating leaving home and who contacted the National Runaway Switchboard before doing so. Referrals are made by the National Runaway Switchboard staff to local runaway centers in their own communities for youth who may need services. The shelters themselves have developed and implemented various activities which are designed to reach potential runaways. These include outreach and public education activities. Outreach workers frequent public areas, shopping malls, parks, transportation centers, where youth congregate, listening to their concerns and providing them with information on available services. Center staff are frequently invited to speak to school classes and assemblies, civic groups and, increasingly, business groups and other community organizations on the problems of runaway and homeless youth and the services which are available to youth and their families within their own communities.

REUNITING RUNAWAYS WITH FAMILIES

Question: Of the families that the Runaway Youth Program serves, how many families are reunited once the child has run away?

Answer: Based on the data collected from the Runaway and Homeless Youth Act funded programs by the Youth Development Bureau's Management Information System, 59.2 percent of the youth served by the programs are reunited with their families. Another 18 percent are placed in stable living arrangements in other areas.

Question: If families are not reunited, what happens to the child?

Answer: Based on the latest data provided to the Youth Development Bureau by the Runaway and Homeless Youth Act-funded projects, the youth who are not reunited with their families after receiving services, 40.8 percent, enter into the following living situations:

Living Situation	Percent of Total Youth Served
Relative's Home	5.0%
Friend's Home	3.7%
Foster Home	4.4%
Group Home	5.0%
Boarding School	.1%
Mental Hospital	.7%
Correctional Institution	1.1%
Independent Living	1.7%
On the Street	8.6%
Other	10.5%

Question: What is the Runaway and Homeless Youth Act funded programs doing, in terms of training, demonstration projects, etc. that could result in more families being reunited?

Answer: The Youth Development Bureau has supported research and demonstration projects designed to strengthen families. During Fiscal Year 1980, eight projects were funded to demonstrate how agencies could expand their services to more effectively address the needs of youth and families experiencing crises associated with adolescent abuse and neglect and parental separation, divorce and remarriage.

Additionally, during the Fiscal Year 1983 Discretionary Grant Funds Program, a request was made for concept papers specifically related to Demonstrations of Innovative Techniques for Reuniting and Strengthening of Families.

The responses have undergone a panel review process and it is anticipated that requests for full proposals will be received in the next two months.

RUNAWAY YOUTH

Question: In the Fiscal Year 1984 budget the Administration proposes a 50 percent cut in runaway youth funding. At the same time, in testimony before the Committee last year you indicated that the number of runaways was increasing. Please explain why you support a cut in this program, if the problem is increasing.

Answer: This request is consistent with the historical pattern of appropriations for this legislation which has been the policy of the several past administrations. Additionally, over the past several years, funding to support runaway centers has become available in the States of Maryland, New York, and Florida which have enacted runaway youth legislation. Very significant amounts of State, local and private funds have been made available to runaway centers in many other States. We believe that States can be more effective in addressing this problem and expect this trend to continue as we implement our policy of encouraging active State participation and involvement in addressing the needs of runaway and homeless youth and their families on both a preventive and an ameliorative basis.

Question: How exactly do you see the Federal role regarding the runaway youth problem?

Answer: We see the Federal role focusing on two major areas. The first area concentrates on encouraging increased involvement by States, localities, and the private sector in addressing problems of runaways. This is being accomplished through the issuance of the program announcements and administrative guidance which specifically invites States, localities, and private sector agencies and organizations to apply for Federal financial assistance under the Runaway and Homeless Youth Act; and by various technical assistance and other efforts such as conferences with State legislators. Our other broad area of activity focuses upon the transfer of technology through the dissemination and utilization of information regarding effective program strategies for providing services to youth and families, both before, during and after a runaway episode, which can be replicated at the State and local level in a cost and service-effective manner. The ten Regional Resource Centers for Children, Youth and Families, supported by the Administration for Children, Youth and Families, are a major mechanism for the dissemination and utilization of this information. The Administration for Children, Youth and Families also supports the Center for Adolescent Mental Health, Washington University, which is designed to assist practitioners, researchers, legislators, policy makers, and the lay public to develop and improve preventive and rehabilitative mental health programs for youth through information synthesis and dissemination.

Question: If you think the runaway youth program can operate effectively with less money, what concrete ideas do you have for achieving savings?

Answer: We are implementing two requirements in the Fiscal Year 1983 funding process which will contribute toward achieving potential savings. In addition to the basic center awards, approximately 100 existing centers will receive "strengthening" grants. These grants, ranging from $10,000 to $50,000, will be used to improve administrative management capabilities including streamlining accounting and financial management procedures. Secondly, all successful applicants funded for the first time in Fiscal Year 1983 will be awarded a grant for a 12 to 17-month project period. The extended project period will provide programs with an opportunity to diversify their funding base. Also, as in the past, we are asking all applicants to address in their proposals the viability of continued service provision once Federal funds are expended.

RUNAWAY AND HOMELESS YOUTH

Question: How can the runaway shelters reach a greater percentage of runaway and homeless youth?

Answer: Centers for runaway and homeless youth have undertaken a wide range of initiatives to reach a greater number of these youth as well as increasing their outreach efforts to youth at risk of leaving home and their families.

Although the shelter capacity of the centers is limited, these community-based programs provided temporary shelter and counseling to 44,000 youth in Fiscal Year 1982 and drop-in services to approximately 133,000 youth. These centers have

developed, however, alternative approaches for providing shelter to youth in need of this service, including the recruitment of host homes. This approach utilizes an extended network of volunteer homes within the community for the temporary placement of youth until family reunification is achieved or other appropriate and permanent housing is secured. The flexibility of a host home network combines needed shelter with the support services for the local runaway and homeless youth center such as individual and family counseling.

Other approaches and activities undertaken by the centers include the use of trained outreach workers who provide information and referral to youth on the street who may be in need of the services offered by runaway and homeless youth centers. Additionally, community education and public awareness efforts, including the use of the media, pamphlets, posters, and presentations and seminars to a wide range of community organizations, agencies, and social service providers, are important and widely used mechanisms for reaching more youth and families in need. One of the areas in which the Office of Human Development Services will support demonstration projects during Fiscal Year 1983 is the development of innovative approaches for outreach services to youth who are initially unwilling to seek services from a runaway and homeless youth center.

The Office of Human Development Services has also encouraged and supported networking initiatives at the State level which are designed in part to improve the ability of runaway service providers to more effectively reach youth in need. We are also committed to improving the operations and technical capacity of the National Runaway Switchboard to provide information and referral services to more youth, families, and runaway and homeless youth centers.

Question: What is the Department of Health and Human Services doing to make the general public aware of its runaway shelters.

Answer: The Department has increased the number of public service spots announced on local and national television and networks to develop an awareness of the services provided by shelters for runaway and homeless youth and their families. The effort has been coordinated through a grant to the National Runaway Switchboard. We have also encouraged the runaway center grantees through the Youth Development Bureau's Youth Services Institute courses of study that emphasize the utilization of local community news media. Some examples of public awareness efforts have been appearances on Coordinating America, The Today Show, Morning Break, and Parade Magazine articles, etc.

Additionally, there have been increased community education and public awareness initiatives by runaway centers to sensitize other community service agencies, professionals, and institutions such as schools to identify, refer, and provide preventive services to youth and families vulnerable to experiencing a runaway problem.

In Fiscal Year 1981, there were eight networking grants made by the Youth Development Bureau that specifically focused on the

coordination of network activities at the local level to establish or strengthen formal working relationships with other youth and family service providers in order to improve service delivery to runaway, homeless and other vulnerable youth and their families.

Although each of the regional or State networks utilized the grants for differing purposes, all of the coordinated networking grantees shared the following common activities including: collecting program, staff development and youth policy information to be widely distributed in newsletter at the local, state and national levels; utilizing the expertise of program staff rather than outside consultants to provide training at workshops; and, developing handbooks or training manuals for youth service workers.

The National Conference of State Legislatures has been disseminating a quarterly newsletter to 7,500 State legislators and their staff on a variety of youth issues and has developed a guide to youth services for State legislators that provides information to share with their respective constituents.

These are some of the continuing efforts that the Office of Human Development Services is making to increase the knowledge of the general public on runaway and homeless youth centers and the services which they provide.

Question: What kind of programs do you have to minimize the number of youth who run away or are put out by their parents each year?

Answer: Minimizing the incidence of runaway behavior or the number of youth forced to leave home by parents is a major concern of the Administration for Children, Youth and Families. The Administration for Children, Youth and Families, the Youth Development Bureau and the centers funded under the Runaway and Homeless Youth Act are utilizing numerous approaches in attempts to reduce the number of youth who run away or are put out of their homes by parents each year.

These efforts include: the support of the National Runaway Switchboard, which provides information and referral services to youth and families prior to as well as during family crises; active outreach by runaway centers to provide preventive counseling and related services to youth and families prior to a runaway episode; increased community education and public awareness initiatives by runaway centers to sensitize other community services agencies, to identify, refer, and provide preventive services to youth and families; the support of networking initiatives at the State level to improve the ability of runaway service providers to reach youth-at-risk; and, the support of a grant to the National Conference of State Legislatures designed to provide technical assistance to State policy-makers regarding the needs of vulnerable youth, to share interdisciplinary information, and to facilitiate the establishment of programmatic linkages.

FY 1983 INCREASE IN RUNAWAY YOUTH FUNDS

Question: Under the Fiscal 1983 Continuing Resolution the Runaway Youth Program received an increase in funding. What plans do you have for spending this money?

Answer: The Fiscal Year 1983 Continuing Resolution provided an appropriation of $21.5 million for the Runaway and Homeless Youth Program.

Based upon current funding plans, this appropriation would be utilized as follows for the support of approximately 201 centers providing temporary shelter care, counseling, and aftercare services at a total funding level of $17 million. This total includes approximately 35 new project starts in unserved communities at a level of $3 million. It will also provide for strengthening center grants to approximately 100 continuation grantees, $3.8 million, designed to strengthen these projects in the areas of management and operations, outreach, or aftercare services. It will support the discretionary research and demonstration projects, $3.55 million, including initiatives in the areas of reuniting and strengthening families, independent living for older youth unable to return home, outreach services and juvenile prostitution and exploitation; and it will provide for the continued support of a Cooperative Agreement with the National Conference of State Legislatures, $240,000, and the National Communications System/National Runaway Switchboard, $700,000.

Question: Will you fund more shelters?

Answer: It is anticipated that approximately 35 new centers for runaway and homeless youth will be funded under the Fiscal Year 1983 appropriation. These centers would be located in communities with a demonstrated need for crisis intervention services for this population. It is expected that the amounts for these new centers will range from $80,000 to $100,000, depending upon the respective State allocation of available funds.

Question: Will you give more funds to existing shelters?

Answer: Approximately $10.2 million will be allocated in Fiscal Year 1983 to provide basic center grants to existing grantees under the Runaway and Homeless Youth Act. Additionally, those centers awarded continuation grants, 166 are eligible, are also eligible to apply for strengthening center grants. These grants, ranging from approximately $10,000 to $50,000, will be awarded to an estimated 100 centers.

Overall, therefore, it is estimated that $14 million will be used to support existing runaway and homeless centers. This represents an approximate increase of 40 percent above the Fiscal Year 1982 level of funding for these centers.

IMPACT OF INCREASED FISCAL 1983 FUNDING FOR RUNAWAY SHELTERS

Question: In the Fiscal Year 1982, Congress appropriated $10,514,000 for the Runaway and Homeless Youth Program. In Fiscal 1983, the appropriation was doubled to $21,500,000. What communities not currently being served by the program will now be served because of the increased funding?

Answer: It is anticipated that approximately 35 new centers will be supported for services in unserved communities at a total funding level of $3 million. It is expected that the project

period for these one-time-only new center grants will be from 12 to 17 months.

Since technical review panels for the review of applications submitted under the Runaway and Homeless Youth Program are conducted in each of the Department's ten Regional Offices, recommendations for these new grants, based in part upon community service needs documented by an applicant, will be made by each Region and awarded with the concurrence of the Commissioner, Administration for Children, Youth and Families. It is anticipated that these recommendations will be made no later than July 15, 1983.

Question: How were these communities chosen?

Answer: No communities have been specifically identified for new centers to be supported under the Runaway and Homeless Youth Act during Fiscal Year 1983. Since the review of applications for funding and recommendations for all center grants are responsibilities delegated to the Administration for Children, Youth and Families' ten regional offices, all recommendations for new center grants will be made to the Commissioner, Administration for Children, Youth and Families, by these Regional Offices, based upon the demonstrated need, provided by applicants for services to runaway and homeless youth in specific communities . Every effort will be made to ensure that these new center grants are located in areas with the greatest demonstrated need for services with priority given to agencies, organizations, State and local governments with past experience in dealing with these youth. The award of new center grants will also be related to Fiscal Year 1983 allocations for each State jurisdiction. It is anticipated that approximately 35 new center grants will be awarded during the current funding cycle.

Question: How will the Department of Health and Human Services use the increased funds to strengthen its existing grantees?

Answer: The Department will utilize the increased funds for the Runaway and Homeless Youth Program to strengthen its existing grantees in several ways.

Through the current funding cycle for Fiscal Year 1983, all currently funded grantees are eligible to apply for funds to strengthen their centers in three specific areas: management and operations; outreach services; and, aftercare services. These grants will be made in addition to the basic center grants for the provision of direct services to runaway and homeless youth. It is anticipated that approximately 100 strengthening center grants will be awarded in amounts ranging from $10,000 to $50,000 for a period of 12 months.

Additionally, under the Fiscal Year 1983 Coordinated Discretionary Funds Program, the Office of Human Development Services expects to award approximately $500,000 under Priority Area 2.2, Program Management Improvements, for grants designed to improve program management practices, including the use of resources, existing technologies, volunteer and community support,

and the dissemination and use of effective techniques for family intervention and crisis counseling.

Discretionary grants will also be awarded for demonstration grants designed to develop and test innovative approaches for reuniting and strengthening families, independent living for older youth, outreach services, and services, both preventive and amelioriative, for juveniles involved in or vulnerable to involvement in prostitution. The Office of Human Development Services also expects to award demonstration grants under Priority Area 1.4, Primary and Secondary Prevention Strategies, which are designed to encourage the development of linkages between runaway youth centers, local schools, and other community agencies and organizations for the early identification of youth in need. These two discretionary areas will be funded at approximately $2.5 million and $300,000, respectively.

All of these initiatives, including other ongoing annual projects such as the Youth Services Institute and the Administration for Children, Youth and Families' Regional Children and Youth Resource Centers, are designed to strengthen grantees through both direct support as well as through the dissemination and utilization of current state-of-the-art information and practices on services to runaway and homeless youth.

Question: With increased Federal funding for Fiscal Year 1983, do you believe runaway shelters will rely less on other sources of income than in the past?

Answer: Although an increased level of Federal funds are available under the Runaway and Homeless Youth Act in Fiscal Year 1983, we do not believe that centers supported under this program will increase their reliance on Federal support.

In its Fiscal Year 1982 Report to the Congress on the status and accomplishments of the Runaway and Homeless Youth Program, now in progress, the following information on funding sources utilized by 148 reporting programs is presented: Runaway and Homeless Youth Act funds, 25 percent; other Federal agency funds, 11 percent; State agencies, 19 percent; county, city, local government agencies, 32 percent; and United Fund, foundations, other donations, 13 percent.

As part of its review of applications for the support of runaway and homeless youth centers in Fiscal Year 1983, one of the criteria utilized to evaluate each applicant agency is the extent to which the applicant can demonstrate its ability to access other resources which can strengthen support for the existing or proposed center's activities to remain a viable organization at the expiration of the Federal funding period.

Additionally, one of the purposes of the strengthening center grants, to be awarded to approximately 100 existing grantees, is to enhance their program management and operations, including the improvement of providing services in a cost-effective manner.

Based upon the experiences of the centers which the Department has funded during the last three years, we anticipate that the type of diversified public and private financial support

for center programs will continue. The Office of Human Development Services will also continue its efforts to assist runaway and homeless youth center grantees in accessing other public and private funding sources.

CHILD ABUSE AND NEGLECT

Question: What has been the effect on the National Center on Child Abuse and Neglect of separately authorizing and appropriating funds for the State grant component and the research and demonstration component?

Answer: There has been no effect on the operation of the National Center on Child Abuse and Neglect. Previously, under the formula stipulated in the Child Abuse Prevention and Treatment Act, as amended, 30 percent of the appropriation approximately $6,800,000 in Fiscal Year 1981 was allocated for the State grant program and a minimum of 50 percent, approximately $12,000,000 in Fiscal Year 1981 was allocated for research and demonstration. Under the separate authorization enacted as a part of the Omnibus Budget Reconciliation Act of 1981, $6,720,000 was appropriated for the State grant program and $9,479,000 for the other programs of the National Center, including research, demonstration, technical assistance and information clearinghouse activities.

Question: Has this resulted in simplifying the administration of these funds, or has it been confusing?

Answer: The separate appropriations have not had any operational effect on the management of the National Center's program.

Question: What improvements could you suggest?

Answer: We are requesting a specific appropriation in Fiscal Year 1984 only for the State grant program. We are requesting that the discretionary activities of the National Center be included as a part of an appropriation for the Human Development Services Research and Demonstration program. This change will allow for planning of research, demonstration, technical assistance and information clearinghouse activities which are both specific to child abuse and neglect and can address other child welfare and youth services program needs.

CHILD ABUSE STATE GRANTS

Question: To what extent has the limited amount of Federal child abuse funds been able to help States develop programs to prevent and treat child abuse and neglect?

Answer: States have used their Child Abuse and Neglect State grant funds in two general ways; to develop and put in place improvements in systems, such as 24-hour hotlines, central registers, procedural manuals for child protective service workers, curricula for preservice and inservice training, and development and broadcast of public awareness media; and to pilot and support start-up periods for innovative prevention and treatment programs. The effectiveness of these clearly defined,

short-term efforts is to be seen in the continuing use of the products and procedures developed and the replication of programs piloted and begun with support of State grants. As an example, between 1978 and 1981, 13 States initiated statewide coverage of 24-hour hotlines for receiving reports of suspected child abuse and neglect, making a total of 35 States that now have this service. We estimate that one-third of the States started up program components which have been continued by other funding sources after the three-year start-up period when Child Abuse and Neglect State grant funds may be used.

Question: How would the States be affected by a leveling-off or reduction of funding under this program?

Answer: We believe that, with level funding, States will be able to continue the kinds of program improvements which they have accomplished in the past under this program. Clearly, a reduction of Federal funding would cause them to seek State or private resources or to reduce some of their efforts.

Question: Given the success of States in expanding their own child abuse prevention and treatment activities with limited Federal funding, why does the Administration persist in wanting to cut this program?

Answer: The Administration is not calling for a cut in the Child Abuse and Neglect State grant program for Fiscal Year 1984. We support level funding for this program, because we recognize how useful it has been in assisting the States to focus resources on this problem.

Question: On the other hand, why continue this program at all?

Answer: The Administration recognizes the necessity to continue a visible role in addressing the tragic and serious problems of child abuse and neglect, to encourage State and local efforts to solve the problem where the problem, is and to facilitate interstate sharing of information, technical assistance and forums for State child protective officials and others to meet State child protective service officials meet with National Center for Child Abuse and Neglect staff twice a year for information exchange in addition, there is the annual conference.

CHILD ABUSE DISCRETIONARY ACTIVITIES

Question: Parents Anonymous and Parents United seem to be good examples of what this Administration is trying to encourage, that is, individuals voluntarily joining together to help each other with their own problems. Are there plans to continue to provide funding to these and other self-help groups?

Answer: Yes, we do plan to continue support for self-help programs.

Question: What is the Federal role in supporting parental self-help groups like Parents Anonymous and Parents United?

Answer: Our current policy is to assist such groups to expand their scope of service rather than providing funds for organizational maintenance. For example, the Office of Human Development Services currently provides support to Parents Anonymous for development of its children's and adolescents' service groups, a self-help approach for children of Parents Anonymous members and other children who have experienced abusive homes. We do not have a current grant relationship with Parents United.

Question: How can this self-help, grassroots approach to providing services be encouraged further by Federal policies and programs?

Answer: The Federal program can encourage the self-help approach to prevention and treatment of child abuse and neglect by supporting such innovations as the "children-serving-children" approach now being implemented and refined by Parents Anonymous; by ensuring organizational communications between self-help national and State organizations and public social service agencies, which can appropriately refer many of their cases to self-help groups; and through providing information and technical assistance to private and voluntary human service organizations in order that they can take on the role of ongoing sponsors of self-help efforts.

CONSOLIDATION OF RESOURCES CENTERS

Question: Please describe the status of the consolidation of the regional child welfare, child abuse, and adoption resource centers?

Answer: As of October 1, 1982 each region now has one Regional Resource Center for Children and Youth Services. Consolidation of the former Centers included transferring staff, equipment, library materials, and furniture from the former centers, integrating staff and program emphases into a single resource center team. The new, expanded Centers have met with the States in their region to determine States' priority needs in providing a continuum of services to children, youth, and families.

Question: Is the consolidation complete?

Answer: Yes, the consolidation of the Regional Resource Centers for Children and Youth Services is completed. There is now one consolidated center in each of Department of Health and Human Services' ten regions.

Question: How much money do you estimate it (the consolidation) will save?

Answer: In Fiscal Year 1982 a total of $4,348,094 was allocated to the three separate groups of resource centers. The total cost in Fiscal Year 1983 for the consolidated center was $3,475,000. The consolidation of these centers had saved $873,094.

Question: What effect will this consolidation have on the services offered by these Centers?

Answer: The consolidated Centers will now focus resources on the priority needs of States in a wide range of children, youth and family services. The centers will be able to help States provide an integrated continuum of services to children, youth and families, not just limiting their activities to those specifically concerned with child welfare training, child abuse and neglect, or adoption. There is a great deal of overlap in these three program areas which necessitated consolidation. For example, there are many youth who are abused; there are youth in foster care who are free for adoption; there are children who are in foster care because they are abused and neglected. In addition to coordinated services to those in child welfare training, the abused and neglected, and those in the adoption system, the consolidated Centers are now also able to address additional issues in the provision of services to children, youth, and families. For example, some of the consolidated centers are working with States on such issues as: youth services, family-based service approaches, foster care and reunification, prevention programs, minority issues, child welfare management systems, private sector involvement in children's and youth services, parent organizations, community-based services, and volunteer groups.

Question: For the record, please list each resource center and the source of its funding?

Answer: Region I New England Resource Center for Children and Families Judge Baker Guidance Center 295 Longwood Avenue, Boston, MA. 02115, (617)232-8390: Christina Crowe, Project Director

Total Grant: $335,000
Source of Funds:
Child Abuse and Neglect-$191,550
426-$95,700
Adoption Opportunities-$47,850

Region II Resource Center on Children and Youth Cornell University, Family Life Development Center, College of Human Ecology, Ithaca, NY. 14853, (607) 256-7794: Frank Barry, Project Director

Total Grant: $344,000
Source of Funds:
Child Abuse and Neglect-$196,550
426-$98,300
Adoption Opportunities-$49,150

Region III Resource Center for Children, Youth and Families, Virginia Commonwealth University, School of Social Work 1001, West Franklin Street, Richmond, VA. 23284 (804) 257-6231: Henry Gunn, Project Director

Total Grant: $400,000
Source of Funds:
Child Abuse and Neglect-$250,000
426-$100,000
Adoption Opportunities-$50,000

Region IV Southeastern Regional Resource Center for Children and Youth Services, University of Tennessee, School of Social Work, 1838 Terrace Avenue, Knoxville, TN. 37996-3920, (615) 974-6015: Jean Blankenship, Project Director

Total Grant: $380,000
Source of Funds:
Child Abuse and Neglect-$217,175
426-$108,550
Adoption Opportunities-$54,275

Region V Region Center on Children and Youth Services, University of Wisconsin-Milwaukee, School of Social Welfare, P.O. Box 786 Milwaukee, WI 53201, (414) 963-4184: Adrienne Haeuser, Project Director

Total Grant: $380,000
Source of Funds:
Child Abuse and Neglect-$217,175
426-$108,550
Adoption Opportunities-$54,275

Region VI Regional Resource Center for Children, Youth and Families, University of Texas at Austin, School of Social Work Austin, TX. 78712, (512) 471-4067: Rosalie Anderson, Project Director

Total Grant: $357,500
Source of Funds:
Child Abuse and Neglect-$204,350
426-$102,100
Adoption Opportunities-$51,050

Region VII Children, Youth and Family Center, University of Iowa, Institute of Child Behavior and Development, Oakdale Campus Iowa City, IA 52319, (319) 353-4791: Charles Abel, Project Director

Total Grant: $257,000
Source Funds:
Child Abuse and Neglect-$144,650
426-$94,900
Adoption Opportunities-$47,450

Region VIII Family Resource Center, University of Denver, Graduate School of Social Work, Denver, CO 80208, (303) 753-3464: Burt Annin, Project Director

Total Grant: $344,000
Source of Funds:
Child Abuse and Neglect-$196,550
426-$98,300
Adoption Opportunities-$49,150

Region IX Consolidated Resource Center for Children and Youth Services, California State University, Los Angeles, 5151 State University Drive, Los Angeles, CA 90032, (212) 224-3283: Shelley Brazier, Project Director

Total Grant: $353,000
Source of Funds:
Child Abuse and Neglect-$201,650
426-$100,900
Adoption Opportunities-$50,450

Region X Resource Center for Children, Youth and Families, University of Washington, School of Social Work, 4101-15th Avenue, N.E. Seattle, WA 98195, (206)545-1669: Dianne Branon, Project Director

Total Grant: $324,500
Source of Funds:
Child Abuse and Neglect-$185,450
426-$92,700
Adoption Opportunities-$46,350

CHILD WELFARE TRAINING

Question: Please describe the activities funded with child welfare training funds during Fiscal Year 1982.

Answer: In Fiscal Year 1982 the Child Welfare Services Training Grant Program awarded $3,500,000 in grants to 108 institutions of higher learning to support projects designed to improve education and training for persons entering or working in the field of child welfare. The Fiscal Year 1982 Teaching Grant Program supported 17 Training Institutes and 12 Technical Assistance Projects. These grants provided short term training and educational opportunities for 2,769 students and agency staff within 27 States and 2 territories. Five teaching grants were awarded to institutions with predominately minority populations. The Fiscal Year 1982 Traineeship Grant Program provided financial assistance for 1,098 students concentrating in child welfare services at 74 schools, were degree candidates, either full or part-time, in Bachelors Degree in Social Work, Master Degree in Social Work, or doctoral programs. An additional 432 were non-degree canidates, working full time in public and private child welfare agencies. Forty one of the Traineeship grants were awarded to Graduate Schools of Social Work, while 33 were awarded to undergraduate institutions. Four traineeship grants were awarded to schools with predominantly minority populations.

Question: What activities will this program support is Fiscal Year 1983 and Fiscal Year 1984?

Answer: The Fiscal Year 1983 Child Welfare Training Grant Program will support education and training projects focusing specifically on Child Welfare services by awarding grants under few priority areas. These include: I-Child Welfare Services Training; II-Leadership Training in Child Welfare; III-State Training Assistance Projects; and IV-Child Welfare Traineeship Projects.

Applicants will complete nationally by priority area. Approximately 40-60 grants will be awarded for a total expenditure of $3,500,000. Eligibility under this grant program has been

broadened to include any accredited institution of higher learning. In considering applications for Traineeship Grants, perference will be given to institutions that award traineeships to persons currently employed in child welfare, however, support for degree students has not been eliminated. The President's budget request for Fiscal Year 1984 proposes a legislative change to include the child welfare training authority in the child welfare services program. This will allow States to use child welfare services funds for training. Since the choice of how these funds will be used in the State's, no information is available for Fiscal Year 1984.

Question: What proportion of Child Welfare Training funds is devoted to undergraduate and graduate students, and what proportion goes to in-service training for individuals already working in the child welfare field?

Answer: During Fiscal Year 1982 approximately one-third of available child welfare training funds ($1,414,479) was devoted to undergraduate and graduate students, while nearly two thirds of available funding was directed to projects providing in-service training and other types of assistance for training individuals already working in the child welfare field.

Question: If child welfare training is put into a child welfare block grant, how can we be sure that States will be able or willing to offer necessary training to students and professionals in child welfare?

Answer: We believe State Agencies are as, if not more, concerned about an adequately trained child welfare work force as are we. If child welfare training funds were put into Block Grants, States may build upon projects and programs initiated under previous Child Welfare Services Training Grants developed in conjunction with State and local child welfare agencies. In Fiscal Year 1983 public agencies in twenty-seven States worked cooperatively with selected schools to develop in-service training institutes and technical assistance projects to address specified child welfare training and staff development needs. Information on the training needs of child welfare staff on a national basis was collected during 1980-81 through two national surveys conducted by the National Child Welfare Training Center in collaboration with the Regional Training Centers in the ten Department of Health and Human Services regions. These surveys are current findings and analyses of State Planning documents such as Child Welfare Services State Plans, State Plans for Foster Care and Adoption Assistance, Child Welfare Services Program Reviews, Section 427 Compliance Reviews can assist States in identifying the priority training needs of students and professionals in child welfare.

ADOPTION OPPORTUNITIES

Question: What activities will be undertaken with adoption opportunities funds in Fiscal Year 1984?

Answer: We are in the process of planning for adoption activities for FY 84. We are considering continuing some of the

efforts already underway. Special consideration is being given to ways in which States can be helped to place more minority children in adoption.

Question: What activities under the initial legislative mandate for the adoption opportunities program have been completed?

Answer: Some of the initial activities are ongoing such as training and education, the adoption information exchange system and the coordination of adoption programs within Department of Health and Human Services. The following activities however, have been completed; Study of Unlicensed Adoption; Data Gathering System and; Model Adoption Legislation and Procedures.

Question: How soon will the rest be completed?

Answer: The National Exchange system is working toward independence in the next two to three years. The other activities are ongoing and address particular areas of need as they arise. For example, issues relative to minority adoption and attitude of workers toward special needs children are being addressed through training and education efforts.

Question: Could your activities on adoption opportunities just as well be sponsored and funded by other programs, such as the Child Welfare Research and Demonstration Program?

Answer: Yes, the activities could be sponsored and funded by other programs. However, the programs would have to focus on training and technical assistance activities rather than research and demonstration in an effort to meet the goals of Public Law 95-266.

ADOPTION OF SPECIAL NEEDS - CHILDREN

Question: How many children nationally meet the definition of "special needs"?

Answer: The definition of "special needs" for children legally free for adoption is left to the States. However, Department of Human Development Services projects that in Fiscal Year 1983 20,000 minority children and 12,000 handicapped children will be legally free for adoption. A current survey and the Voluntary Cooperative Information System will provide current data.

Question: How many of these "special needs" children do you project will be placed through the Adoption Assistance Program?

Answer: We estimate that an average of 3000-4000 children per month will be receiving payments under the Title IV-E Adoption Assistance Program in Fiscal Year 1983.

Question: How can this number be increased?

Answer: This number can be increase through public awareness of the need for the adoption of special needs and minority children and expand and improve recruitment campaigns for potential adoptive families.

Other methods include increased States' participation in and implementation of the Adoption Assistance Program, Title IV-E, by encouraging States to set targets for planning for minority and special needs children; Assisting States in including in their State plans a special focus on the placement of minority children; upgrading the skills of adoption workers and supervisors who are placing special needs and minority children, and assisting the regional resource centers for children and youth to use available resources more effectively on issues pertaining to the adoption of special needs and minority children.

Question: What barriers remain in State law and agency practices that work to prevent the adoptive placement of a special needs child?

Answer: Many States have not sufficiently focused on adoption of special needs children as a critical issue, and have not developed objectives, nor committed adequate resources to increase placement of these children.

Many States have not focused on the special efforts which must be made to place minority children. These children tend to wait the longest for homes, and to receive the least service. It has been well established that through recruitment of families, hiring of minority staff, review of practice and policies for ethnic and cultural sensitivity, training of workers and supervisors that minority children can be placed at a reasonable rate. But it takes a special, focused, organizational effort to achieve these changes. States need to continue to make every effort to improve their case plans, case review systems and dispositional hearings, in order to assure that waiting children are tracked and moved through the system. Adoption practices and policies frequently have become outdated. The matching process for parents and children is sluggish and endless. Adoption of special needs children is too labor intensive and the costs per child are extremely high. Issues of parent preparation and homestudy requirements, pre and post adoption services, staffing, attitudes of workers toward the children and potential parents all need to be improved. The per child cost must be reduced and the process. Many workers and supervisors are not prepared to handle the adoption of special needs children. They do not believe the children are adoptable and tend to think that a solid foster home is better than risking permanent placement. We have not solved the problem of viewing the country as a national resource for the placement of waiting children. While we recognize that children should be placed as close to their current communities as is appropriate, there is still not enough sharing of waiting adoptive families and children across State lines, or across county lines in many cases. Interjurisdictional barriers keep children in foster care longer than they need to remain. There is a problem for families who adopt special needs children for whom medical assistance is important. If these families move across State lines, the current policy requires them to continue to use the Medicaid care made available to them by the State in which they adopted. Providers in the State to which they move usually refuse to honor the out of State Medicaid card, thus rendering it useless. This is a problem which must be resolved if families are going to feel comfortable adopting the child with special medical needs.

STATE ADOPTION ASSISTANCE PROGRAMS

Question: All States were to have an Adoption Assistance program by the end of Fiscal Year 1981. Did all the States accomplish this?

Answer: Yes. All States have submitted Title IV-E plans that included an adoption assistance program effective in the first quarter of Fiscal Year 1983.

Question: What are the consequences for States that failed to meet this deadline?

Answer: All States met this requirement. However, a State that had not met the requirement would have been ineligible for receiving any Title IV-E funds including both foster care and adoption assistance.

Question: How many States are expected to participate in the Adoption Assistance Program in Fiscal Year 1983? In Fiscal Year 1984?

Answer: We expect 35 to 40 States to participate in Fiscal Year 1983. Through the beginning of the third quarter of Fiscal Year 1983, 35 States have submitted estimates of expenditures for adoption assistance. In Fiscal Year 1984, we expect that number to increase to 40 or more States.

Question: What is the projected Federal spending under the Adoption Assistance Program in Fiscal Year 1983 and Fiscal Year 1984?

Answer: In 1983 $5 million is available from the 1983 appropriation and $4.5 million is available from previous appropriations. In 1984 the request is $5 million. If, for some reason these amounts are not sufficient to pay claims, available options for paying these claims will be reviewed.

Question: What is the projected State spending?

Answer: The projected State share of title IV-E Adoption Assistance expenditures for Fiscal Year 1983 and Fiscal Year 1984 is about $7.5 million in Fiscal Year 1983 and $10 million in Fiscal Year 1984.

Question: How many children will be placed under the Adoption Assistance Program in Fiscal Year 1983 and Fiscal Year 1984?

Answer: We estimate that an average of 3000-4000 children per month will be receiving payments under the Title IV-E Adoption Assistance Program in Fiscal Year 1983 and 4000-6000 in Fiscal Year 1984.

ADOPTION ASSISTANCE PROGRAM

Question: How many States participated in the Adoption Assistance Program during Fiscal Year 1982?

Answer: Eleven States filed expenditure reports for the Adoption Assistance Program for Fiscal Year 1982.

Question: How many children were placed?

Answer: Among the 11 States which filed claims the average monthly number of children for whom payments were made was 1,326.

Question: What was the average payment?

Answer: The Federal share of the average monthly payment was $122.

Question: What was total Federal spending under this program in Fiscal Year 1982?

Answer: The Federal share of expenditures reported for Fiscal Year 1982 was $1.95 million.

Question: What is the total State spending?

Answer: The State share of Title IV-E-Adoption Assistance expenditures in Fiscal Year 1982 was approximately $1.8 million, according to surveys conducted by the National Child Welfare Training Center in collaboration with the Regional Training Centers in the ten Health and Human Services regions. These surveys and current findings and analyses of State Planning document such as Child Welfare Services State Plans, State Plans for Foster Care and Adoption Assistance, Child Welfare Services Program Reviews, Section 427 Compliance Reviews can assist States in identifying the priority training needs of students and professionals in child welfare.

PROGRAMS FOR THE AGING: STATE AGENCY ACTIVITIES

Question: What has been the result of the Administration on Aging initiative to increase the amount of program income from contributions made by older persons who receive services under Title III Supportive and Nutrition Services programs?

Answer: We are very pleased with the results of the initiative to increase program income expenditures under Title III programs. Program income expenditures, which consist mainly of contributions made by older persons, increased by $22 million (28 percent) from Fiscal Year 1981 to Fiscal Year 1982. This is particularly impressive since the initiatives to increase program income and to improve the program and financial management of State and area agencies were not instituted until the middle of Fiscal Year 1982.

Question: Do you think the States will be able to achieve the goal of collecting program income from contributions of older persons in an amount equal to 20 percent of Title III allotments by the end of Fiscal Year 1982?

Answer: Based on the results of our initiatives in Fiscal Year 1982, we are confident that we will achieve the goals established for Fiscal Year 1983. Data reported by the States for Fiscal Year 1982 reflect that program income increased from $78.9 million in Fiscal

Year 1981 to $100.9 million (18 percent of Title III allotments) in Fiscal Year 1982.

Question: What was the amount of program income for Fiscal Year 1982?

Answer: Data reported by the States for Fiscal Year 1982 reflect that program income expenditures were $100.9 million, an increase of 28 percent from the amounts reported in Fiscal Year 1981.

Question: What are the major barriers faced by States in increasing the amount of program income from contributions for services received by older persons?

Answer: We do not feel there are any major barriers to increasing the level of program income from contributions for services received by older persons. One minor barrier that has come to our attention is the possible misunderstanding on the part of older persons as to the nature of the contribution. Service providers have not clearly understood or described the voluntary nature of the contribution to older participants. One of the first steps we took in launching the program income initiative was to distribute model posters for use in various service settings which emphasize the voluntary nature of the contribution.

PROGRAMS FOR THE AGING: SUPPORTIVE SERVICES AND SENIOR CENTERS

Question: Fiscal Year 1982 funds for Supportive Services and Senior Centers for the elderly decreased by 4 percent from the Fiscal Year 1981 level of $252 million to $240 million. The Fiscal Year 1983 appropriation and Fiscal Year 1984 request remain at $240 million. What has been the impact of funding reductions in the Supportive Services Program?

Answer: There has been no significant impact on the Supportive Services Program resulting from the reductions in funds between Fiscal Year 1981 and Fiscal Year 1982. In Fiscal Year 1981, an estimated 8.9 million persons received services under this program; in Fiscal Year 1982, States reported that an estimated 9.2 million persons were served.

Question: What is your estimate of the number of services reduced?

Answer: States reported that an additional 300,000 persons received supportive services in Fiscal Year 1982 over the estimated 8.9 million served in Fiscal Year 1981.

MEANS TESTING AGING PROGRAMS

Question: In view of the budgetary problems facing the country, and limited funding for many programs what would be the impact of changing current Older Americans Act policy to require mandatory fees for supportive services or employ means testing for certain high cost supportive services supported by the Act?

Answer: We have never required mandatory fees for supportive services or employed means testing for any services supported by the Older Americans Act. We anticipate any requirement incorporating

means testing or fee schedules would inhibit many older persons from participating in Older Americans Act programs because of the negative stigma associated with these activities.

MINORITY PARTICIPATION IN AGING PROGRAMS

Question: What is your response to findings of the recent Commission on Civil Rights study indicating that minority groups are under-represented in several aspects of the operation of the Title III Program - including participation rates of older persons in services, employment in area agencies on aging, and in the award of funds to minority provider organizations?

Answer: The Administration on Aging has consistently addressed the targetting of resources toward low-income older persons, and Census Bureau data clearly indicates that older persons in greatest economic need also tend to be minorities. In nearly all Program Instructions, Technical Assistance materials, and other guidance materials or managerial initiatives referring to the use of resources or which discuss program development, we have consistently indicated that special consideration be given to assure adequate services to low-income and minority older persons.

With regard to the employment of minorities, the Older Americans Act requires State agencies to meet Merit Systems Standards. This requirement also applies to area agencies if the area agency is a public agency. These standards have created problems for State and area agencies in carrying out affirmative action plans because a number of minority persons lack the educational credentials or particular background required for various positions. Minority applicants all too frequently do not appear on the "best qualified" list of applicants for a particular position, especially in top managerial positions. As a result, progress in hiring minorities has been difficult to achieve. In an effort to overcome some of the barriers created by the Merit System, the Administration on Aging has worked with the Office of Personnel Management to improve State and Area Agency performance in affirmative action efforts. States have made a number of changes in job descriptions, recruiting efforts and improvements in training staff once they were hired.

Relative to the receipt of services by older persons, the Administration on Aging's data for 1982, indicates that 18 percent of the participants receiving nutrition and supportive services are minorities. Of the 1,800 full-time State employees, 19.3 percent are minorities and of the 11,000 Area Agency staff, 19.3 percent are minorities.

Question: Do you believe that this six-city study is representative of the nation?

Answer: We believe that a vast number of relevant factors were either overlooked or not discussed in the final Civil Rights report. The Study contains a significant amount of factual information; however, factors such as the availability of minorities in the labor force and the proportion of minorities residing in the planning and service areas studied are not discussed in the context of successful achievements by the area agencies. We have some question as to whether the sites selected are actually representative of the "typical" area agency on aging and its efforts. We would also like

to call your attention to the fact that all older persons are eligible for the receipt of services without regard to status, and State and area agencies are required to give preference to those older persons with greatest economic or social need. Census Bureau data indicates that many older persons with economic need also tend to be minorities.

The data provided in the answer to the previous question presents a picture of the accomplishments to date. These findings are supported in a recent study on the above items by Community Research Applications, Inc. (CRA). In 1980-81 this organization compiled information from 387 Area Agencies, with site visits to 16 area agencies. We believe that this report more accurately reflects the actual representation of minority participation in the Title III program. Most Area Agencies have outreach strategies for reaching minority elderly and use minority-relevant strategies to encourage minority participation in the nutrition program.

Question: What steps are you taking to assist States in improving the minority group participation rate under the Older Americans Act Programs -- both in terms of services to minority older persons as well as employment of minority persons in the aging services network?

Answer: The Administration on Aging has funded a number of discretionary grant activities to assist and promote minority representation and involvement in the program. Some of the awards were made to national minority organizations for provision of technical assistance to State and area agencies in planning and outreach efforts, and in designing programs appropriate to special needs of minority elderly. These organizations have helped translate program materials into a variety of languages and have assisted in building relationships between minority communities and service providers, providing a direct link to a particular minority or ethnic group. We have worked with these groups to hold national conferences to discuss national issues and policy, and to provide training and technical assistance to the aging network.

We are working to improve the rate of older minority participation in the program. We plan to hold a series of minority work group sessions in our regional offices during 1983 and 1984. We will involve staff from all levels of the aging network, to propose and implement strategies for improving minority participation in the program.

ELDERLY EMPLOYMENT PROGRAM

Question: Your budget includes $277 million to replace the Labor Department's older worker program, which is currently funded at $319 million. In March 1983 Congress indicated its support for the existing Labor Department program by expanding its funding of the "Jobs" supplemental, from $282 million up to $319 million. Why are you asking the Appropriations Committee to abolish the existing Labor Department program, and give you a blank check for a replacement program for which you haven't even submitted proposed legislation detailing what you have in mind?

Answer: The budget justification submitted in January of 1983 is based on a legislative proposal to discontine the Community Serv-

ices Employment Program for Older Persons under the Department of Labor, and include a new program under the Administration on Aging. Details of the new program cannot be discussed until the legislative proposal has been finalized. A draft legislative proposal has been submitted to the Office of Management and Budget for review and concurrence.

Question: If your proposal were enacted, can you assure us that none of the elderly persons currently enrolled in the Labor Department programs would be laid off?

Answer: Details of the new program cannot be discussed until the legislative proposal has been finalized. A draft legislative proposal has been submitted to the Office of Management and Budget for review and concurrence.

Question: Would contracts with such groups as the Farmers' Union and the Retired Teachers' Association, organizations that currently administer the bulk of the Labor Department Program, be terminated under your proposal?

Answer: Details of the new program cannot be discussed until the legislative proposal has been finalized. A draft legislative proposal has been submitted to the Office of Management and Budget for review and concurrence.

HOME-DELIVERED VERSUS CONGREGATE MEALS FOR THE ELDERLY

Question: Given a fixed amount of funding available for nutrition services, do you think that a greater amount of funding should be made available for home-delivered meals by proportionately reducing the amount available for congregate meals?

Answer: Section 308(b)(5) of the Older Americans Act allows States to transfer funds between the allotments made for congregate and home-delivered nutrition services. States are making use of this provision in the Act to increase the amounts available for home-delivered nutrition services. Transfers made by the States are as follows:

	FY 1982	FY 1983
Transfers from Congregate Nutrition Services to Home-delivered Nutrition Services	$10,500,000	$16,400,000
Transfers from Home-delivered Nutrition Services to Congregate Nutrition Services	400,000	400,000
Net transfers	10,100,000	16,000,000

In view of the transfers allowed by the legislation, and the fact that States are making use of this provision, we believe that there is no need for changes in the proportion of funds appropriated for congregate and home-delivered nutrition services.

Question: Has the demand for home-delivered meals been increasing over the last few years?

Answer: Yes. Data reported by the States indicate that not only the number of home-delivered meals has increased, but that the proportion of meals served which are home-delivered has increased. The following data has been submitted by the States:

	Annual Increase in Number of Home-delivered Meals	Percent Increase	Percent of all Meals served
FY 1978	7,679,000	51	17
FY 1979	8,197,000	36	20
FY 1980	5,358,000	17	22
FY 1981	8,887,000	24	24
FY 1982	5,245,000	12	26

ELDERLY NUTRITION/UNIT COSTS

Question: What was the average increase in the cost of congregate and home-delivered meals from 1982 to 1983?

Answer: Fiscal Year 1983 financial and program performance data from which unit costs are derived will not be available until December 1983. However, between 1981 and 1982 changes in unit costs were as follows:

	FY 1981	FY 1982	Change
Congregate Meals Costs	$2.54	$2.63	+$.09 (+4%)
Home-delivered Meals Costs	2.07	1.96	-.11 (-5%)

We believe that the increase in the costs of congregate meals compares very favorably with the increase in the cost of living during the period which was seven percent.

Question: What steps has the Administration on Aging taken to assist nutrition projects to reduce the average cost per meal?

Answer: The Administration on Aging has contracted with the Community Nutrition Institute (CNI) to develop a "Nutrition Providers' Guide to Fiscal Management and Accounting", a manual which includes best practice information on ways to improve provider cost control systems. For Fiscal Year 1982, this guide was distributed to all local nutrition services providers, area agencies on aging, and State agencies on aging and was the substantive base for delivering regional fiscal management training for approximately 350 State and local network staff. In Fiscal Year 1983, CNI is preparing assistance materials on "cost containment." These materials will be distributed to all States and will provide the basis for carrying out on-site technical assistance to those States which request help in this area.

In addition, Phoenix Systems, through contracts with the Administration on Aging in Fiscal Years 1982 and 1983, provided regional training to improve State and local contributions systems. Also, a complete set of financial management manuals for States, area agencies, and service providers has been distributed with appro-

priate training to State agencies regarding their use by Birch & Davis, Inc.

PROGRAMS FOR THE AGING: GRANTS TO INDIANS

Question: What has been the effect of the recent change in the law eliminating the age 60 requirement for participation in the grant program for Indian Tribal organizations?

Answer: As a result of the 1981 amendments to the Older Americans Act, services under Title VI of the Act are no longer limited to Indians 60 years of age or older. The grantees which provide services under Title VI have opted to define "older" Indian as follows:

	Number of Grantees
Age 60+	41
Age 55+	35
Age 50+	8
Age 45+	1
Total	85*

* There were 83 grantees funded in Fiscal Year 1983. However, two of the 83 grantees funded have different definitions of older Indians in their two sites.

Question: Is there any evidence of increased demand for services as a result of this change?

Answer: The change did not take effect until December of 1981. We do not have data regarding services under Title VI during that period.

Question: What will be the scope of the evaluation of the grant program to Indian tribal organizations?

Answer: The objectives of the evaluation, being conducted by Native American Consultants, Inc. (NACI) under a contract with the Administration on Aging, which terminates on October 31, 1983, are to determine how completely the mandated purposes of Title VI of the Older Americans Act have been fulfilled; to identify factors which promote or inhibit the effectiveness of the program; and, to recommend steps at the project, tribal, and national levels to improve the Title VI program.

The following list contains the major issues being addressed in the evaluation:

- What programs and administrative structures have been put in place?
- To what extent is the program meeting the needs of older Indians?
- Does the program reflect the different cultural attributes of this population?

- What types of technical assistance and training have been provided? What is needed? Is it helpful?
- What problems or barriers to the effective implementation of the program have been encountered?
- How does this program mesh with other Federal and tribal programs? What other resources are available and utilized?
- How is this program viewed by the participants? Does it make a difference in their lives?
- What changes in administrative practices, regulation, or legislation are needed to improve the program?

Since the beginning of the study, November 1, 1982, the contractor has completed a comprehensive review of a sample of 43 grant files out of a total of 83 native American grantees participating in the Title VI Program. These files included application documents, reports on technical assistance and other documents relative to the Title VI program.

The contractor is making visits to 12 project sites to interview local program officials and program participants. The first six site visits will be completed by the end of May 1983 and the second six visits will be completed by the end of August 1983.

A Technical Advisory Committee has been established to advise the Administration on Aging about the overall direction of the Program and specific issues raised by the evaluation.

PROGRAMS FOR THE AGING: NATIONAL CLEARINGHOUSE

Question: In view of the fact that authority for the National Clearinghouse for the Aging was eliminated by the 1981 amendments to the Older Americans Act, what use was made of the Fiscal Year 1982 continuing appropriations amount of $1,721,000 for this program?

Answer: Of the $1,721,000 appropriated in Fiscal Year 1981 for the National Clearinghouse on Aging, $790,000 was used for evaluations, as authorized by section 206(g) of the Act. The remainder of the balance was reprogrammed.

PROGRAMS FOR THE AGING: FEDERAL COUNCIL ON AGING

Question: What activities has the Federal Council on Aging undertaken during the last fiscal year?

Answer: The Federal Council on the Aging (FCA) met four times during 1982: May 19-20; July 21-22; September 15-16; and December 8-9. All meetings were held in Washington, D.C. In order to keep apprised of the wide range of issues affecting the elderly, the Council called upon a variety of experts for presentations at Council meetings. Topics included: the Older Americans Act and the role of the Administration on Aging; Preliminary Findings of the National Commission on Social Security Reform; the Older Worker and Employment; Mounting Costs of Health Care--Medicare and

Medicaid; HUD Programs for Housing and the Elderly; U.N. World Assembly on Aging; U.S. Senate and House of Representatives activities concerning the elderly; etc. The Council established several committees of Council members. Two of the committees, Housing and Reauthorization of the Older Americans Act, were given high priority.

The Housing Committee acted to support recommendations in both the President's Commission on Housing Report and the 1981 White House Conference on Aging's Housing Committee Report. On June 4, 1982 the Housing Committee sponsored a meeting with Congressional staff, federal agency officials and representatives of the private sector to discuss a variety of housing issues. The Housing Committee met again on November 12, 1982 to provide a forum for exchanging ideas between the Department of Housing and Urban Development and non-profit sponsors of Section 202, federally subsidized housing for the elderly.

The Committee on Reauthorization of the Older Americans Act has undertaken a review of the Act and related issues. The Council sponsored a Roundtable at its December 8, 1982 meeting and heard presentations from 13 national aging organizations concerning reauthorization of the Act. The Reauthorization Committee is compiling information from additional organizations. This data will be taken into consideration as the Council develops its recommendations to the President and the Congress.

In addition, the Chairperson of the FCA served on the U.S. delegation to the U.N. World Assembly on Aging held in Vienna, Austria from July 26-August 6, 1982.

Question: Other than its mandate to hold quarterly meetings and to submit a report to Congress has the Council been able to carry out any other of its responsibilities under the Act, given its recent level of appropriations?

Answer: The FCA has been able to function, as mandated by Congress, within the current level of appropriation. The annual report informs and advises the President on matters which the Council identifies as currently relevant to the needs of the elderly. In addition, the Commissioner on Aging has met several times with the Council. The Council reviews and evaluates Federal policies regarding the aging on an ongoing basis, formulating comments and recommendations for both Congress and the President as appropriate. Several meetings and a Roundtable discussion provided forums for the exchange of information and the identification of areas of concern regarding issues on aging.

Question: What is the estimate of the funding needed to hold quarterly meetings?

Answer: The cost of travel and expenses for 15 Council members totals approximately $10,000 for each quarterly meeting held in Washington, D.C.

Question: Please describe how the Discretionary Research and Demonstration grants under the Office of Human Development Services were administered in Fiscal Year 1982.

Answer : In Fiscal Year 1982 the Office of Human Development Services initiated a coordinated planning and decision-making approach that involved the collective efforts of HDS programs in a grant award process that commonly targeted resources on priority State and local human service issues.

In addition, a number of categorical discretionary activities were combined under the Coordinated Discretionary Funds Program announcement to achieve the most comprehensive means of planning and supporting HDS program needs, as well as State, local and community interests.

Each categorical program encompassing discretionary resources participated equally in the planning process that identified priority issue areas. In addition, each formulated a program plan that identified project activities and priority areas for the use of program dollars in areas outside the Coordinated Discretionary Funds Program announcement. Funding decisions were made by the Assistant Secretary, HDS, and program commissioners in full compliance with authorizing legislation.

Question: How was this different from previous years?

Answer : The major differences in the administration of HDS' Fiscal Year 1982 Discretionary Research and Demonstration grant activities were:

a. the issuance of a coordinated multi-program announcement inviting preapplications from State, local and nonprofit agencies and organizations in relation to priority areas they helped identify;

b. the joint involvement of HDS program administrators in the review and grant award decision-making process; and

c. the expanded use of joint funding across programs in the award of projects that will benefit multiple populations and program operations.

Question: What was the purpose of administering these funds this way?

Answer : The Coordinated Discretionary Funds Program was designed to minimize duplication of effort among categorical programs while targeting limited dollars to priority assistance needs identified by the States and localities.

The overall objective of the HDS Coordinated Discretionary Funds Program was:

a. To increase accountability through the direct involvement of program heads in the review and decision-making process; and

b. To maximize the impact of available dollars in problem areas common to multiple programs (due to the reductions in the level of discretionary funds available).

Question: Has this purpose been accomplished?

Answer : Yes. The purpose of the Coordinated Discretionary Funds Program has been accomplished as evidenced by:

a. the response to the coordinated program announcement and issue areas identified therein, resulting in approximately 5,600 preapplications received in HDS; and

b. the award of 35 multi-program sponsored grant awards.

Question: What problems have arisen from this change and what are you doing about them?

Answer : No problems have arisen from this change.

Question: Please provide for the record a list of all grants awarded in Fiscal Year 1982 under the Office of Human Development Services Discretionary Funds Program, indicating which legislative authority or authorities the funds fall under.

Answer : A list of all grants awarded in Fiscal Year 1982 under the Office of Human Development Services Discretionary Funds Program is attached.

Question: How many grants awarded in Fiscal Year 1982 under the Office of Human Development Services Coordinated Discretionary Funds Program used funds from more than one program?

Answer : Thirty-five grants under the Coordinated Discretionary Funds Program used funds from more than one program.

Question: Are any special accounting or auditing procedures used for these areas?

Answer : No. Standard accounting and auditing procedures used by Health and Human Services for all grants are used for this program.

The Office of Program Development, HDS, clears all grants prior to processing by the Division of Grants and Contracts Management to ensure that appropriate levels of funds and other accounting data are accurately reflected as identified in each program's financial plan.

Grantees are required to undertake an audit (by an independent auditor) at least every other year of the duration of their project/grant. The results of the audit are submitted to the Division of Grants and Contracts Management, HDS.

In addition, a Grant Officer may request a special audit based on his/her review of a grantee's financial status reports, given reasonable indication that there is misuse of grant funds.

Question: In projects that received grant funds from more than one program, have there been problems with grantees receiving conflicting guidance or information from different program officials?

Answer : To date there have been no reported incidents of grantees receiving conflicting guidance or information from different program officials.

The Office of Human Development Services' grants administration policies require that a Grants Officer (within the Office of Management Services) and a Project Officer (within the appropriate HDS program office) have joint responsibility for administering and monitoring a grantee's performance. The Grants Officer is responsible for interpreting and carrying out HDS grants management policies and procedures.

The Project Officer has primary responsibility for programmatic aspects of the project (i.e., assuring compliance with terms and conditions of the grant, site visits, review of performance reports, etc.).

Although multiple funding sources were used to award grants in the Fiscal Year 1982 Coordinated Discretionary Funds Program, only one Project Officer was assigned responsibility for project management/monitoring of the grant.

Usually this is a staff person of the program contributing the most financial support. Input from other programs participating in the grant is coordinated by this individual; however, he/she singularly is responsible for interacting with the grantee.

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HDS PROGRAM AUTHORITIES

Administration on Aging (AoA)	Older Americans Act of 1963, Title IV.
Administration on Developmental Disabilities (ADD)	Omnibus Budget Reconciliation Act of 1981; Developmental Disabilities Assistance and Bill of Rights Act, as amended.
Administration for Native Americans (ANA)	Native American Programs Act of 1974; the Omnibus Reconciliation Act of 1981.
Administration for Children, Youth and Families	
Head Start (HS)	Head Start Act; Omnibus Budget Reconciliation Act of 1981.
Child Welfare Research (426)	Social Security Act, as amended Title IV., Part B, Section 426.
Child Abuse and Neglect (CAN)	The Child Abuse Prevention and Treatment Act Title I, as amended.
Adoption Opportunities (AO)	Child Abuse Prevention and Treatment and Adoption Reform Act of 1978.
Section 1110 of Social Security Act (HDS)	Social Security Act, as amended Title XI, Section 1110.

HDS JOINT DISCRETIONARY PROGRAM
FY 1982 PROJECT AWARDS
PROJECT AWARDS AND SPONSORS

Priority Area	Grantee and Grant #	1982	AoA	ADD	ANA	HS	426	CAN	AO	HDS
1.1	Maryland Dept. of Human Resources 90PD86511/01	213,338					213,338			
1.1	Hennepin County Minnesota Comm. Svcs. 90PD86513/01	106,250					106,250			
1.1	Wis. Dept. of Health and Social Svcs. 90AJ10003/01	309,686	200,000	61,000						48,686
1.1	Family Builders of Colorado 90DD0017/01	75,000		75,000						
1.1	New Jersey Dept. of Human Services 90PD86512/01	230,795					230,795			
1.4	Arizona Dept. of Economic Security 90NJ0001/01	109,063			75,063					34,000
1.4	Connecticut Office of Pol. and Planning 90PD10030/01	84,975								84,975
1.4	South Dakota State Planning Bureau 90PD10032/01	56,100								56,100
1.4	Tex. Advisory Comm. on Intergov Relats. 90PD10026/01	50,558								50,558

Priority Area	Grantee and Grant #	1982	AoA	ADD	ANA	HS	426	CAN	AO	HDS
1.4	Pa Gov's Office of Policy and Planning 90QJ1002/01	200,000	100,000							100,000
1.5	Minn. Dept of Pub Welfare 90PD10028/01	135,000								135,000
1.5	Commonwealth of Mass — Elder Affairs HDJA 3153	180,000	180,000							
1.5	USC-Ctr for Health Services 90PD86006/01	244,927					244,927			
2.1	Nat. Fire Protection Association 90DD0029/01	99,921		99,921						
2.1	American Bar Association 90DJ0001/01	287,732	72,700	80,000			77,197			57,835
2.1	California Dept. of Developmental Svcs 90QJ0002/01	303,750		151,875			151,875			
2.1	Quinnalt Indian Nations 90PD86514/01	50,000					50,000			
3.1	New Jersey Dept. of Community Affairs 90DD0028/01	98,769		98,769						
3.1	Mississippi Dept. of Welfare 90PD10025/01	124,725								124,725
3.1	Nat. Assn. of St Units on Aging (NASUA) 90AM0040/01	345,760	345,760							

Priority Area	Grantee and Grant #	1982	AoA	ADD	ANA	HS	426	CAN	AO	HDS
3.2	Mich Evaluation Resource Center 90PD10033/01	215,721								215,721
3.2	Center for Human Services Mgmt, Inc. 90CW666/01	216,605				216,605				
3.2	N Charles M.H. Research and Training 90AM0043/01	112,799	112,799							
3.2	Foster Grandparent of Pittsburg 90PD86007/01	4,300					4,300			
3.3	Bureau of Social Science Research 900J1007/01	325,000		20,000		81,250				223,750
3.4	National Governors Asan. 90PD10024/01	295,000								295,000
4.1	Univ of MD Center for Productivity 90CJ55/01	199,054				132,054	67,000			
5.1	Rand Corporation 90CJ56/01	241,036				154,351				87,487
6.1	Vol and Info Center 900J1004/01	20,000				10,000				10,000
6.1	Nat Coal Hispan MH&Hum Svc Org (COSSMHO) 900J1008	129,999	55,000				30,700			44,300
6.1	Ark Gov Office of Volunteer Citizens 90AJ1006/01	144,355				91,882				52,473

Priority Area	Grantee and Grant #	1982	AoA	ADD	ANA	HS	426	CAN	AO	HDS
6.1	Cayuga County Action Program 90CW686/01	19,080				19,080				
6.1	North Texas Area Food Bank 90PD10036/01	148,541								148,541
6.1	Vol Action Center of Champaign County 90PD86005/01	14,068					14,068			
6.1	Research Triangle Inst HDJA 4068	179,266	179,266							
6.1	Regional Inst of Social Welfare 90PD10031/01	75,595								75,595
6.1	Ecumenical Comm for Migrant/Comm Concers 90CW698/01	42,630				42,630				
6.1	Chapel Hill Carrboro Schools 90CW687/01	72,079				72,079				
6.1	United Way of St. Cloud Area 90PD10029/01	57,318								57,318
6.1	Community Council, Inc. 90AJ10007/01	106,560	50,340	22,074						34,146
6.1	City of Pasadena, Risks & Grants Mgmt. 90PD86004/01	99,500					99,500			
6.2	Dept of Hum Svc. Bur of Maine's Elderly 90AR0043/01	150,771	150,771							
6.2	Council of Jewish Organs 90PD10039/01	100,000								100,000

Priority Area	Grantee and Grant #	1982	AoA	ADD	ANA	HS	426	CAN	AO	HDS
6.2	Permanent Charity Fund of Boston 900J1003/01	105,700				40,000				65,700
6.2	Phoenix So Community MH Center 90DD0020/01	28,000		28,000						
6.3	Council of State Planning Agencies 90AM0045/01	103,252	103,252							
6.3	Wisc. Dept of Health and Human Services 90AM0038/01	99,022	99,022							
6.3	Gov's Advis Comm Child Dev Prog 90PD86516/01	72,552					72,552			
8.1	Univ of Wash Inst on Aging/Lg Term Care HDJA 0424	133,053	133,053							
8.1	Inupiat Comm of the Artic Slope 90DD0022/01	118,887		118,887						
8.1	Vinland Nat Center 90DD0018/01	125,000		125,000						
8.1	Mountain States Health Corp., Boise 90AM0044/01	171,245	171,245							
8.1	NY Council on Children and Families 90PD86500/01	150,000					150,000			
8.1	Alex. Va. Dept of Social Services 90PD10034/01	162,000								162,000
8.1	Navajo Community College 90PD86505/01	111,685					111,685			

Priority Area	Grantee and Grant #	1982	AoA	ADD	ANA	HS	426	CAN	AO	HDS
8.1	N. Amer Council on Adoptable Children 90PD86504/01	111,315					111,315			
8.1	Eastern Montana Univ College of Ed. 90PD86510/01	26,361					26,361			
8.1	Suomi College, Hancock, 90AM0037/01	160,450	160,450							
8.1	College of St. Scholastica 90AM0036/01	63,737	63,737							
8.1	Mifflin-Juaniata AAA 90AM0041/01	15,410	15,410							
8.1	Univ of Wash. Dept of Spec Educ 90DD0021/01	20,000		20,000						
9.1	Pa State University 90PD86507/01	99,978					99,978			
9.1	Cornell University 90CA893/01	95,000						95,000		
9.1	Council of Community Services 90PD86506/01	117,453					117,453			
9.1	Temple University 90OJ2001/01	154,000		31,200			122,800			
9.1	NJ Dept. of Human Services 90CA914/01	65,600						65,600		
9.1	Barry University HDJA 2299	78,800		39,400				39,400		

Priority Area	Grantee and Grant #	1982	AoA	ADD	ANA	HS	426	CAN	AO	HDS
9.2	Nat Center for St. Cts, Williamsburg 90AJ1001/01	179,562	143,701	35,861						
9.2	Protec and Advocacy Agency of Hawaii 90AJ1000/01	156,654	120,799	35,855						
9.2	Nat American Indian Court Judges Assoc. 9000J02000/01	101,970			23,970		78,000			
9.3	Wayne State University 90AR0040/01	153,742	153,742							
9.3	Proj LUCK Metr Svc Dis Cri Jus Plan Unt 90CA892/01	199,923						199,923		
9.4	Colorado Dept of Social Services 90PD86508/01	151,547					151,547			
9.4	Wisc. Dept of Health and Soc. Svcs. 90AJ1004/01	158,197	128,281	29,916						
9.5	Ramsey County Community Human Svcs 90PD86008/01	205,490					205,490			
10.1	Kans Comm for Prevention of CAAN 90PD86515/01	49,750					49,750			
10.1	Fairfax County 90PD86503/01	83,856					83,856			

Priority Area	Grantee and Grant #	1982	AoA	ADD	ANA	HS	426	CAN	AO	HDS
10.2	IL Dept of Children and Family Svcs. 90C0210/01	100,000							100,000	
10.2	University of North Carolina 90C0208/01	150,000							150,000	
10.2	Nat Black Child Devel Institute 90C0206/01	133,430							133,430	
10.2	Spaulding Southwest 90C0207/01	71,270							71,270	
10.2	Creative Learning Institute 90C0211/01	206,608							206,608	
10.2	Mich. Dept. of Mental Health 90C0209/01	79,072							79,072	
10.3	Calif Protection and Advocacy 90DD0025/01	100,000		100,000						
10.3	N.M. Protection and Advocacy 90DD0019/01	100,000		100,000						
10.4	Goodwill Industries HDJA 2568	155,238		155,238						
10.6	Adoption Center of Delaware Valley 90C0212/01	350,000							350,000	

Priority Area	Grantee and Grant #	1982	AoA	ADD	ANA	HS	426	CAN	AO	HDS
10.7	Reg I - Judge Baker Guidance Center HDJA 4502	335,000					95,700	191,450	47,850	
10.7	Reg II - Cornell Univ HDJA 3407	344,000					98,300	196,550	49,150	
10.7	Reg III - Va Commonwealth Univ HDJA 1746	400,000					100,000	200,000	50,000	
10.7	Reg IV - Univ of Tennessee HDJA 5040	380,000					108,550	217,175	54,275	
10.7	Reg V - Univ of Wisconsin at Milwaukee HDJA 1684	380,000					108,550	217,175	54,275	
10.7	Reg VI - Univ of Texas at Austin HDJA 4654	357,500					102,100	204,350	51,050	
10.7	Reg VII - Univ of Iowa HDJA 0559	257,000					94,900	114,650	47,450	
10.7	Reg VIII - Univ of Denver HDJA 1352	344,000					98,300	196,550	49,150	
10.7	Reg IX - Calif State Univ, Los Angeles HDJA 3165	353,000					100,900	201,650	50,450	
10.7	Reg X - Univ of Washington HDJA 0425	324,500					92,700	185,450	46,350	
10.8	Univ of Alaska, ISER 90NA0100/01	248,562			248,562					
10.8	United Indian Development Assoc HDJA 0104	159,495			159,495					

Priority Area	Grantee and Grant #	1982	AoA	ADD	ANA	HS	426	CAN	AO	HDS
10.8	Council of State Planning Agencies 90QJ1000/01	200,000				50,000				150,000
10.9	Nat Assn of Counties 90CW679/01	359,951				359,951				
10.9	State of Tenn Children Svc. Commission 90CW685/01	202,740				202,740				
10.9	Educational Alliances, Inc. 90CW680/01	293,475				293,475				
10.10	Yale Univ Hall of Grad Studies 90CW676/01	225,000				225,000				
10.10	Miami Valley Child Development 90CW669/01	94,000				94,000				
10.12	High/Scope Educ Research Found HS 90CW695/01	399,699				399,699				
10.12	S.W. Educ Devel Lab ES 90CW692/01	250,000				250,000				
10.13	Comm. Renewal Team of Greater Hartford 90CW684/01	141,979				141,979				
10.13	Commwealth of Mass Office for Children 90CW693/01	140,644				140,644				
10.13	Gov's Commission for Children, Youth 90CJ54/01	118,700	13,700			105,000				

Priority Area	Grantee and Grant #	1982	AoA	ADD	ANA	HS	426	CAN	AO	HDS
10.13	Pa Dept of Public Welfare 90CW683/01	247,208				247,208				
10.14	Wisc Dept of Health and Soc. Svcs. 90AM0042/01	99,883	99,883							
10.14	Mich Office of Services to Aging 90AR0044/01	102,500	102,500							
10.14	The Rock Creek Foundation 90DD0023/01	100,000		100,000						
10.15	Univ of Illinois 90DD0015/01	84,209		84,209						
10.15	Univ of Michigan 90DD0016/01	147,505		147,505						
10.17	Child Care Assoc of Dallas 90CJ50	211,654				151,654	60,000			
10.17	Wheelock College 90PD86501/01	44,554					44,554			
10.17	Austin Child Guidance & Eval Center 90CW670/01	107,416				107,416				
10.17	Foundation of Human Services, Inc. 90CJ51/01	139,994				69,994	70,000			
10.18	Pa Dept of Aging 90AT0070/01	100,000								

Priority Area	Grantee and Grant #	1982	AoA	AMD	ANA	HS	426	CAN	AO	HDS
10.18	Univ of D.C. HDJA 1854	100,000								
10.18	Atlanta Univ 4340	100,000								
10.18	Miami Univ HDJA 0659	100,000								
10.18	Univ of S.C. HDJA 4660	25,545								
10.18	Hunter College/Cuny HDJA 2005	88,368								
10.18	Univ of S Calif/Psych HDJA 0704	100,000								
10.18	Univ of Texas/Arlington HDJA 2432	100,000								
10.18	Elgin Community College HDJA 2615	72,067								
10.18	Livingstone College HDJA 4505	58,450								
10.18	Weber State College HDJA 0343	78,502								
10.18	Clark College HDJA 3440	69,241								
10.18	Ohio Univ HDJA 2452	100,000								

Priority Area	Grantee and Grant #	1982	AoA	ADD	ANA	HS	426	CAN	AO	HDS
10.18	Univ of Arizona 90AT0072/01	35,300								
10.18	Va Commonwealth Univ 90AT0071/01	99,991								
10.18	Oregon State Univ HDJA 4280	76,236								
10.18	North Texas State Univ HDJA 1451	100,000								
10.18	Univ of Michigan HDJA 4474	100,000								
10.18	Norfolk State Univ HDJA 2279	90,494	2,590,569 (total for 10.18)							
10.18	Fordham Univ HDJA 3769	100,000								
10.18	Hampton Institute HDJA 3646	100,000								
10.18	Univ of MD/Aging Center HDJA 3611	95,000								
10.18	Memphis State Univ HDJA 1217	27,426								
10.18	Va Union Univ HDJA 0939	56,029								
10.18	Wichita State Univ HDJA 4522	96,085								

Priority Area	Grantee and Grant #	1982	AoA	ADD	ANA	HS	426	CAN	AO	HDS
10.18	Madonna College HDJA 4154	100,000								
10.18	Grambling State Univ HDJA 4345	74,613								
10.18	Wayne County Community College HDJA 4962	100,000								
10.18	Middlesex Community College HDJA 3427	49,721								
10.18	St. Scholastica College HDJA 1858	100,000								
10.18	Univ of Bridgeport HDJA 1800	97,571								
11.1	The Contact Center 90PD10037/01	125,626								125,626
11.1	Nat Center for Home Equity Conversion 90AR0046/01	118,500	118,500							
11.1	Assoc for Habilitation & Employ of DD 90DD0024/01	154,653		154,653						
11.1	American Indian Law Center HDJA 1368	92,030			92,030					
11.1	University of Southern California 90PD10035/01	149,031								149,031
11.1	Community College of Greater NY 90OJ1005/01	60,631				30,631				30,000

Priority Area	Grantee and Grant #	1982	AoA	ADD	ANA	HS	426	CAN	AO	HDS
11.1	City of NY Dept Housing Preserv & Devel 90AJ1003/01	109,933	89,933							20,000
11.1	N.Y. City Fire Dept 90AM0035/01	140,520	140,520							
11.1	Union Carbide Sr. Retired Exec Corps 90AM0039/01	100,000	100,000							
11.1	Corp for Independent Living, Hartford 90DD0027/01	100,000		100,000						
11.1	Nat Office of Samoan Affairs 90PD10027/01	74,267								74,267
11.1	Community Action Program of Evansville 90CW690/01	166,336				166,336				
11.1	Univ of Michigan 90CW691/01	29,763				29,763				
11.1	The Psychological Center 90AJ1006/01	60,149	45,149							15,000
11.1	Johns Hopkins Univ. 90PD86509/01	74,436					74,436			
11.1	NYS Council on Child & Fam 90PD86502/01	110,000					110,000			
	Total FY '82 Obligations:	23,351,850	6,040,082	2,014,363	599,120	3,925,421	4,029,727	2,324,923	1,590,380	2,827,834

167 : Projects Awarded

Question: "What are the Administration's major initiatives for the Developmental Disabilities Basic Grants and Advocacy Programs?"

Answer: The intent of the Developmental Disabilities Assistance and Bill of Rights Act is to improve the availability and quality of services for developmentally disabled people. The Basic State Grant program is the major component of the legislation in support of this effort. The major initiatives of the Basic State Grant Program are:

1. To improve availability, quality and coordination of services through:

   a. Reducing dependency and increasing self-sufficiency of developmentally disabled people;

   b. assisting States to provide the most appropriate care by reducing institutional placement and facilitating development of alternative family and community living arrangements for developmentally disabled people;

   c. assisting States to improve their capacity to provide services in the least restrictive environment;

   d. targeting services to previously unserved and underserved developmentally disabled people;

   e. expanding services to strengthen family care givers, informal care givers and providers of foster care; and

   f. increasing number and quality of volunteers providing services to developmentally disabled people.

2. To assure protection of rights for developmentally disabled citizens through State Protection and Advocacy services and State Developmental Disabilities programs.

3. To encourage individualized program plans as a basis of providing and evaluating services for developmentally disabled people.

4. To enhance the capacity of States to manage programs for developmentally disabled people.

The major priorities of ADD relative to improving the protection and advocacy program nationally are:

1. To increase the capacities of State Protection and Advocacy systems to develop, exchange and share resources for advocacy for developmentally disabled persons; and

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2. to focus these resources more effectively on unserved and underserved developmentally disabled persons.

At the beginning of the Protection and Advocacy program, the staffs of the new State offices frequently needed support from individuals and organizations which had greater experience in the area of advocacy for the rights of developmentally disabled persons (e.g., American Bar Association). Staff of our State Protection and Advocacy systems are now, however, well versed in all aspects of their work and each P&A has experience and resources which could prove invaluable to staff of other Protection and Advocacy agencies .

Consequently, our focus has shifted from providing external support to the Protection and Advocacy agencies to focusing on increasing the capacity of these agencies among themselves, i.e. developing key strategies, training materials and other services. We are presently working to complete a telecommunications network which will give each agency the ability to communicate with other State Protection and Advocacy systems by electronic mail. This telecommunication network should be the basis for long-term technical assistance exchange among the States.

Over the past two years ADD and the Office for Civil Rights, HHS, have collaborated on developing model Protection and Advocacy projects for reaching persons with developmental disabilities who are also members of minority groups. This year, through the Office of Human Development Services (OHDS) discretionary program, we are funding two model Protection and Advocacy projects - in New Mexico and California - to assist developmentally disabled Native Americans, Asians and Spanish-speaking children and adults to move to the least restrictive community placement.

These "minority outreach" projects have stimulated considerable interest within the Protection and Advocacy community in developing effective activities on behalf of minority persons with developmental disabilities. To promote further Protection and Advocacy activities in this area, OHDS has funded a small technical assistance exchange project geared specifically toward providing assistance from the HHS-funded minority outreach Protection and Advocacy projects to other State Protection and Advocacy systems which are developing their own minority initiatives.

We are also exploring ways to assist State Protection and Advocacy systems to advocate the rights of developmentally disabled persons who commit offenses bringing them under the jurisdiction of criminal justice systems. This effort includes, in part, the development of models for training developmental disabilities, judicial and criminal justice personnel to deal with the developmentally disabled offender in ways which maximize habilitative intervention.

Question: What have been the major positive and negative changes in the program which may be attribute to the revised definition of the term "Developmental Disability?"

Answer: The change in the definitior of developmental disabilities resulted in two positive changes in the program. First, eliminating the categorical types of disabilities from the definition brought about the inclusion of severely disabled persons as a part of the target population who do not have mental retardation, cerebral palsy, epilepsy, or autism. Second, the addition of the criterion that persons have three functional limitations caused State Planning Councils and Protection and Advocacy Agencies to focus their planning and advocacy efforts on behalf of that population which is most in need of services.

It created a shift of emphasis in identifying persons in need of services from one where diagnosis was the criterion to one in which function was the critical factor and consequently focused on the most severely handicapped.

The one possible negative factor is that the new term "substantial functional limitation" does not adequately define severity.

Question: "How has this change affected Service Delivery?"

Answer: It is difficult to assess the specific impact of the change in definition on service delivery since the new definition was enacted concomitantly with the new requirement that States select among four priority services areas. Any changes in type of service programs supported with Federal Developmental Disabilities funds may be equally attributable to emphasis on a priority service area or attention to the new service population.

We are aware however, that there has been a shift to programs that are more intensive and more directed toward the long-term service needs of a more severely disabled population.

This shift in programs is consistent with the identified needs of severely handicapped persons under the functional definition.

Question: What progress has been made in developing a clear and consistent focus in the University Affiliated Facilities Program?

Answer: The Commissioner of the Administration on Developmental Disabilities sponsored a series of workshops last Fall to consider the mission and accomplishments and future directions for the University Affiliated Facilities Program.

Participating in the Workshops were a group of experts in the field, including representatives from the University Affiliated Facilities and their Satellite Centers, other components of the developmental disabilities program, and the major Federal funding agencies for the program. The discussions

during the workshops focused upon the resources, capacities, and functions of the University Affiliated Facility program with the intent of proposing directions for the program, in terms of its structure and administration, for 1983 and beyond.

The Workshop group has not yet completed its full report.

Question: What are the Administration's plans regarding continued funding for University Affiliated Facilities?

Answer: Continuation awards were made last year (FY 1982) to each of the University Affiliated Facilities (UAFs) which complied with the Congressionally mandated standards for UAFs. Each of the thirty-six (36) UAFs met the standards and, therefore, received continuation awards. Continuation awards were also made to each of the five (5) Satellite Centers.

In 1983, all existing grantees will compete for continuation funding. They were asked to submit applications which will be reviewed by panels against specific criteria which were given to the grantees in advance with their application materials.

We will initiate a three (3) year funding cycle for the University Affiliated Facilities and Satellite Centers. This means that, pending the availability of funds, awards made will be for three-year project periods. The awards for the next two years will be non-competitive and will be made based on continued satisfactory performance.

We are in the process of negotiating the transfer of two of the grants to other institutions which have the resources and commitment to continue the UAF functions within those same States. The grant currently at Kean College in New Jersey is being transferred to the Rutgers Medical School. The grant at the University of Michigan will be transfered to Wayne State University.

NATIVE AMERICAN JOINT FUNDING PROJECTS

Question: The Catalog of Federal Domestic Assistance description of Native American programs refers to Joint Funding Projects. With which programs and agencies have you been involved under the Joint Funding authority?

Answer: Projects funded by the Administration for Native Americans (ANA) are eligible for inclusion in Joint Funding projects, under the authority of the Joint Funding Simplification Act (JFSA). In past years, ANA has participated in three such projects. The Administration for Children, Youth and Families, the Department of Housing and Urban Development, the Law Enforcement Assistance Administration, and ANA supported a Joint Funding project for the Salt River Pima-Maricopa Indian community. The Administration for Children, Youth and Families, the Bureau of Indian Affairs, the Economic Development Administration and ANA jointly funded a project for the Pueblo of Zuni. The Bureau of

Indian Affairs and ANA jointly funded a project for the Cheyenne and Arapahoe Tribe.

Question: How much was spent in the past fiscal year for each of these programs?

Answer: During the past fiscal year, the Administration for Native Americans (ANA) has not participated in any projects under the authority of the JFSA. However, in fiscal year 1982, ANA participated in 24 interagency agreements involving $2,332,618 in ANA funds under the authority of the Economy Act (31 USC 686) and Section 812(c) of Public Law 93-644.

Question: What portion of these Joint Project funds came from the Administration for Native Americans?

Answer: In fiscal year 1982, the Administration for Native Americans (ANA) did not participate in any projects funded under the JFSA.

TRANSFER OF INDIAN ACTIVITIES

Question: The recently enacted "jobs" supplemental contains a provision to prevent transfer during fiscal 1983 of general administration of programs authorized under the Native American Programs Act to the Bureau of Indian Affairs. Do you still plan to go ahead with this transfer in fiscal 1984 by administrative fiat, or will you now submit a legislative proposal to the authorizing Committees?

Answer: Based on the authority currently provided under Section 812 of Public Law 93-644 and the Economy Act (31 USC 686) the Department will continue to propose the transfer of the administration of grants to Federally-recognized tribes through the Bureau of Indian Affairs (BIA) in fiscal year 1984.

Question: Can you tell us specifically what activities and staff of the Administration for Native Americans would be eliminated or reduced and what would be transferred to the Bureau of Indian Affairs, if your proposal were carried out?

Answer: At the present time there is a proposed overall staff reduction in the Office of Human Development Services (HDS). However, no specific program levels have been developed for the Administration for Native Americans (ANA) or other units within HDS. There are no plans to eliminate ANA. The Administration for Native Americans will work with the Bureau of Indian Affairs (BIA) in such activities as: the development of program announcements; project monitoring; training and technical assistance; and, related operating procedures. It will also administer the planned phase-out of non-federally recognized grantees, including urban Indians, rural off-reservation Indians without federal recognition and Native Hawaiian groups over the next three years. Budget requests for these groups will be reduced by one third in fiscal year 1984 and another third in fiscal year 1985 and will be zero in fiscal year 1986.

Question: What is the rationale for phasing out assistance to non-federally recognized tribes and organizations, even though the law mandates services to these groups?

Answer: The Native American Programs Act of 1974, P.L. 93-644, as amended, authorizes rather than mandates that non-federally recognized groups are eligible to be considered for financial grant awards. The proposed phase-out for non-federally recognized grantees includes urban Indians, rural off-reservation Indians without federal recognition and Native Hawaiian groups. Current projects to non-federally recognized groups are expected to accomplish results that are lasting and do not require ongoing Federal support. An additional consideration is that communities served through these projects fall within the jurisdiction of State and local governments. These groups will be eligible to be considered under the reduced levels in fiscal years 1984 and 1985, and are also eligible to be served through block grants and categorical programs to states, and discretionary programs to state or local governments.

URBAN INDIANS

Question: Your budget appears to propose elimination of services to urban Indians and Native Hawaiians. Do you know if Administration for Native Americans programs for urban Indians comprise most of the Federal assistance to these Indians, or are there other agencies engaged in substantial assistance programs to urban Indians?

Answer: At present there are other agencies, in addition to the Administration for Native Americans (ANA), that provide federal assistance to urban Indians. These are: Indian Education Programs in the Department of Education; Office of Indian and Native American Programs in the Department of Labor; the Social Services Division of the Bureau of Indian Affairs in the Department of the Interior; and, the Indian Health Service in the Department of Health and Human Services.

COMMUNITY WORK EXPERIENCE PROGRAMS

Question: Which States have exercised their new authority to require most able-bodied parents in the program of Aid to Families with Dependent Children (AFDC) to work enough hours at the minimum wage to earn their family's welfare check?

Answer: As of April 1, 1982, areas within 20 States have operational Community Work Experience Programs (CWEPs). These States are: Alabama, Arkansas, California, Colorado, Georgia, Idaho, Iowa, Kentucky, Michigan, Minnesota, New York, North Carolina, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Virginia, Washington, and West Virginia.

Five additional States plan to implement CWEP in 1983. These States are: Kansas, Nebraska, New Mexico, Pennsylvania, and Vermont.

Question: What work has been performed in these "workfare" programs and at what cost?

Answer: Workfare participants have performed a wide variety of public services including weatherization of low-income housing, medical transportation for senior citizens, law enforcement, building restoration, and building and grounds maintenance.

Implementation of CWEP helps States reduce their budget deficits while continuing to provide valuable public services. We anticipate that States will save approximately $2.50 in payments for every $1 that they spend on program administration. Federal matching is available at 50 percent for necessary administrative costs (with a $25 monthly cap on reimbursement of expenses directly incurred by participants). States report average administrative costs ranging from $20 to $40 per month per participant. States may keep these costs low by tapping other resources. For example, some States are using Title XX funds to support child care activities or are asking sponsors to pick up some participation costs such as workers' compensation and excess transportation costs.

JOBS SEARCH REQUIREMENTS

Question: Which States have exercised their new authority to require that Aid to Families with Dependent Children applicants search for a job while their application is pending?

Answer: Three States have operational employment search programs. These States are: Massachusetts, Vermont, and Washington.

Six States definitely plan to implement employment search programs. These States are: Kansas, New York, Oklahoma, Oregon, Texas, and Virginia.

Eight States are actively and seriously considering implementing employment search programs. These States are: California, Colorado, Idaho, Illinois, Minnesota, Ohio, Utah, and Wisconsin.

Question: To what extent, if any, have workfare programs and job search requirements for applicants deterred persons from enrolling in the Aid to Families with Dependent Children Program?

Demonstration programs in States such as Oregon and Oklahoma make it clear that work programs involving job search or workfare requirements reduce the AFDC caseload, both through individuals' finding jobs and through diversion from workfare of those who are unwilling to comply with the requirements.

Although this combined effect is substantial, research findings are not currently available which can consistently separate the job finding and deterrence effects. The research objectives of some of our CWEP demonstrations include attempts to measure more precisely the deterrence effects of work requirements.

HEAD START

Question: You are requesting an increase of $62 million for Head Start. However, you propose eliminating all $370 million for the community services agencies. The community services agencies

often run Head Start programs. How do you expect to maintain or increase Head Start programs while eliminating the agencies that operate them?

Answer: We expect that many States and local jurisdictions will provide funding for their community services agencies, and that some of them will find support from other sources as well. In these cases there will be no impact on Head Start at all. In other cases, even if the community services agencies have no other source of funding, they may choose to reorganize their structure and remain the Head Start grantee, so long as the Head Start Parent Policy Council approves of any personnel and budget actions that may be involved.

For the extreme case, Congress has provided in the current Head Start legislation, an orderly process for continuing Head Start services in a community in which the current grantee, by virtue of a change in funding for other Federal programs, no longer exists. Where it happens, a successor agency operated in substantially the same manner, such as a delegate agency to the current grantee would then by law be given priority in the designation of a Head Start agency.

Question: You propose a 43% cut in State Developmental Disabilities Services. Is this proposal backed up by some dramatic drop in the number of children with Developmental Disabilities or the cost of serving them?

Answer: The reduction of do ars to support the Developmental Disabilities (DD) Program in FY 1984 has little relevance to the delivery of services to developmentally disabled individuals as this program is, as you know, not a direct service one nor is its amount in terms of dollars of such scope to have a significant national impact in service delivery.

We recognize the magnitude of the problem in that we estimate that there are 3.9 million developmentally disabled people in the United States. We are aware that it is a $10 billion problem with almost $6 billion being provided by State dollars. Of the Federal $4.5 billion expended in programs and services for the developmentally disabled, only 1.4% of that represents the DD Program budget. Over 80% of the Federal effort is financed by the Social Security Administration; the balance by Special Education, Rehabilitation Services, Public Health and Headstart.

The intent of the DD legislation is to provide a means, at the State level, to orchestrate other State/Federal programs inducing them to include the developmentally disabled in their activities and to influence the States and communities to provide services at the community level.

We are convinced that more than a decade of experience in stimulation and demonstration funding has provided sufficient "best practice" models. States have been highly successful in using Federal dollars to develop models to complement and

augment services for the developmenally disabled. Current assessments assure us of this.

We are considering proposing to allow the States to choose how they will spend their allotments in the future. We anticipate that many will choose to enhance the operational activities of the State Councils in orchestrating and administrative influencing within the States to provide an array of services mandated in the legislation:

Federally Assisted State Programs (as mentioned in the DD Act and as presently titled)

1)	Education for the Handicapped	Special Education
2)	Vocational Rehabilitation	Vocational Rehabilitation
3)	Public Assistance	AFDC
4)	Medical Assistance	Medicare/Medicaid
5)	Social Services	Title XX (block grant)
6)	Maternal & Child Health	Maternal and Child Health Services (block grant)
7)	Crippled Children's Services	Crippled Children's Services
8)	Comprehensive Health	Comp. Public Health Services (block grant)
9)	Mental Health	Community Mental Health/ Community Support Program

AGING

Question: What is the status of your proposal to transfer elderly nutrition programs from the Department of Agriculture to the Department of Health and Human Services?

Answer: We are not proposing a transfer of elderly nutrition programs from the Department of Agriculture. The budget justification submitted in January of 1983 is based on a legislative proposal to transfer the appropriation for the Commodities or Cash-in-lieu of Program, currently under the Department of Agriculture, to the program budget of the Administration on Aging. For those few States who wish to continue to receive commodities, rather than cash, a mechanism will be established by the Administration on Aging to allow purchase from the Department of Agriculture.

Question: Have the authorizing committees shown any inclination to act on it?

Answer: The legislative package has not been submitted to the authorizing committees. Draft legislation is currently under review at the Office of Management and Budget.

REDUCTION IN FUNDS

Question: You propose a $55 million cut in Aging programs. How do you justify that in terms of the number or needs of the elderly?

Answer: The reduction of $55 million consists of reductions in programs under the Administration on Aging as follows:

State Agency Activities	$1,745,000
Congregate Nutrition Services	28,125,000
Home-delivered Nutrition Services	3,875,000
Sub-total, Nutrition Services	32,000,000
Supportive Services for Employment and Economic Development	4,850,000
Training, Research, and Discretionary Projects and Programs	17,175,000
Total	55,770,000

Overall budget reductions were necessary as a key element in support of the President's economic program. As a result, our FY 1984 budget request was formulated to place priority on the maintenance of service levels. Reductions are proposed only in those areas where we believe even with a funding reduction, we can maintain services reviews at the FY 1983 level and in programs which do not directly provide services. The reductions in State Agency Activities; and Training, Research and Discretionary Projects and Programs are examples of the policy to place priority on the maintenance of services as these programs do not directly provide services to older persons.

Over the past several years the State and area agencies on aging have maintained an excellent record of increased productivity which has more than compensated for the rate of inflation. For example, between Fiscal Year 1981 and Fiscal Year 1982 the average cost of a meal served in a congregate setting increased only four percent despite an inflation rate of more than seven percent.

The average cost of a home-delivered meal decreased five percent during this period. With the current rate of inflation moderating we believe the progress made by State and area agencies regarding productivity increases will continue. In FY 1982 States transferred approximately $5,000,000 from Title III-C, Nutrition Services, to Title III-B, Supportive Services, and still increased the total level of meals served by 3 million.

REGIONAL OFFICES OF THE OFFICE OF COMMUNITY SERVICES

Question: If it becomes evident that elimination of these Regional Offices has damaged delivery of anti-poverty services, will you support their reinstatement?

Answer: OCS has no direct role related to local organizations, such as Community Action Agencies (CAAs), that provide anti-poverty services in their communities. With the passage of the Community Services Block Grant Act, CAAs and other eligible entities receive their funding from the States. These grantees now look to State administrators of the CSBG for technical assistance, monitoring, and support that they need in carrying out their CSBG-funded activities. The OCS Headquarters staff continues to provide technical assistance to States as they have since OCS was created at the beginning of FY 1982. Through the CSBG, grantees have even closer ties to their funding source than they would if funding were provided through Regional Offices or Headquarters as was the practice under the Community Services Administration (CSA).

The discretionary grants program is directly managed by an OCS Headquarters unit. These 84 grantees are funded for specific activities and are funded once rather than on a continuing basis. Regional Office management of this program is not warranted.

Once the close out of old CSA grants was completed in March of 1983, there no longer was a function for the Regional staff.

GRANTEES UNDER THE COMMUNITY SERVICES BLOCK GRANT PROGRAM

Question: What has been the reaction of States, Community Action Agencies and public interest groups to the closing of the Regional Offices?

Answer: The reaction has been minimal. We have received some Congressional inquiries which forwarded concerns of a handful of CAAs who felt that the closing of the Regional Offices would deprive them of needed services, assistance and advice. However, these concerns are based on a misunderstanding of the role of the OCS Regional Offices. These offices were established to carry out the closeout of CSA grants and grantees; they were not responsible for funding grantees of the CSBG. Local organiztions receive their CSBG funding from the States, and the States therefore are responsible for providing any technical assistance and monitoring required by the CAAs and other local CSBG grantees. The OCS Headquarters staff continues to provide technical assistance to the States in support of block grant programs.

In addition, OCS employees were concerned and OCS received some Congressional inquiries about the status of OCS Regional employees after March 31, 1983 when the closeout activities were virtually completed. All OCS Regional Office employees have been detailed to other positions within DHHS, or, in a few cases, to other Federal agencies. We hope that many of these employees will be picked up as permanent employees in their new assignments and the Department is making every effort to see that this happens.

Question: How many Community Action Agencies are there?

Answer: Under the Community Services Block Grant Act, States are not required to report information concerning local grantees. At the time the federal Community Services Administration closed on September 30, 1981, approximately one thousand Community Action Agencies (CAAs) were operating. State plans indicated that in most cases States were planning to continue CAAs. We have found that to be the case in States in which we've conducted Program Implementation Assessements to date.

Question: How many entities are operating programs with Community Services Block Grant funds?

Answer: The Office of Community Services has made FY 1983 grant awards to every State and territory, exccept for Alaska, Guam and American Samoa. These three jurisdictions have not filed complete applications for FY 1983 CSBG funds. OCS has also awarded funds to 103 Indian Tribes and tribal organizations.

Question: How many local programs are receiving funds appropriated under the CSBG?

Answer: The Community Services Block Grant, as amended, requires the States to use nine-tenths of their CSBG allocations to make grants to "eligible entities" as defined by law. These entities are primarily Community Action Agencies which received federal funds during FY 1981. The law does not, however, require States to provide funds for every eligible entity within their borders. The law also does not require States to report to the Office of Community Services about which eligible entities receive funding under the program. However, again we know that States have for the most part continued to fund CAAs.

Question: How many discretionary program grantees are there?

Answer: There are 84 grantees in the FY 1982 Discretionary Grants Program. In addition, OCS transferred $500,000 of FY 1982 discretionary funds to ACTION to support the Vietnam Veterans Leadership Program. The solicitation of proposals is now underway for the FY 1983 Discretionary Grants Program. OCS published an announcement in the Federal Register on March 23, 1983, inviting proposals for the $25 million now available. Proposals must be submitted by June 1, with grant awards to be made in September. OCS estimates that as many as 1,000 applications may be received and that 75 to 85 grants will be awarded. OCS has transferred $500,000 of FY 1983 discretionary money to ACTION for the Vietnam Veterans Leadership Program.

Question: Are there more Community Action Agencies now then there were in October, 1981?

Answer: Recognition of an agency as a CAA was a function of CSA which was abolished on September 30, 1981. Therefore, there could not be recognition of any new CAAs since then. Under the CSBG, States can create new grantees in addition to the CAAs. However, since States must for FY 1983 use 90 percent of their allocations to make grants to eligible entities--primarily CAAs which received funding in FY 1981--and since States may use 5 percent of

their funds for administration, that leaves only 5 percent with which States may set up new grantees. We are not aware of any State that has done so.

CSBG OVERSIGHT

Question: The Community Services Block Grant is nearly two years old. What oversight has been conducted to ensure that States are complying with the provisions of the Act?

Answer: Oversight of State CSBG activities has been accomplished in three major ways.

Program Implementation Assessments (PIAs) are conducted in at least ten States each year. The assessments are based on the assurances in the CSBG legislation. Data are collected through an intensive on site review of State administrative, financial, and programmatic activities. Based on the findings, OCS follows up on any issues which require further investigation.

OCS reviewed the FY 1982 reports submitted by States which detail how they expended their FY 1982 CSBG funds. These reviews are designed to ensure that State activity is consistent with the plans the States submitted prior to the funding year and any other requirements of the CSBG legislation.

A procedure for the investigation of complaints has been developed by OCS.

CLOSEOUT OF CSA GRANT FUNDS

Question: We have been informed that in closing out small CSA grants to Community Action Agencies, OCS has dropped the Economic Opportunity Act's requirement for a complete audit of funds. Instead, up to $90,000 can be "certified" by the personnel of each affected grantee as having been properly spent.

On what basis was the Economic Opportunity Act requirement dropped?

Answer: The Certification of Revenues and Expenditures procedure applies primarily to grantees who have already completed an annual audit and still have a small amount of money remaining. In these cases, the requirements of the Economic Opportunity Act have been completely met. This procedure is used when a grantee's balance is $90,000 which remains to be closed out after its last annual audit. In a small number of cases, we are allowing grantees to use the Certification process for small grants up to $50,000. In fact, most of these grants are under $25,000. Careful consideration went into the development of this procedure, and the CSA/OCS Inspector General participated in its development and ultimately approved this procedure. This procedure is not used with grantees where instances of fraud or abuse are suspected, or where a grantee has had financial management problems in the past. In these cases, the grantee must have a full audit regardless of the size of the grant or the cost of the audit. The Certification procedure is used only with grantees that have a clear record of fiscal integri-

ty. Because of the accelerating costs of CPA audits, we do not believe it is in the interest of the Federal government to spend a significant portion of these small grants on audit activities for these fiscally-responsible grantees. We believe the funds are much more effectively used to directly serve the needs of the poor.

Question: What is the legal basis for the new "Certification of Expenditures?"

Answer: As mentioned earlier, OCS requires a full-scope audit for each Community Action Agency and only then allows the small unexpended balances to be closed out through a Certification of Revenues and Expenditures. The CSA/OCS Inspector General agreed to the use of this procedure when the grantee had a record of sound fiscal management. It is important to note that OCS specifically authorized the firm of Arthur Young & Company to randomly review the quality and integrity of the Certifications in several States. The grantees were selected by lot and were unaware when they prepared the Certifications that they would subsequently be visited by Arthur Young. I am pleased to report that the Certifications were found to be prepared properly and the financial records completed with integrity. It is a credit to the CAAs that they have been able to use the Certification process so effectively and thereby retain maximum use of funds for services to the needy.

Question: What is the total amount of grant funds, nationwide that has thus been exempted from a proper audit?

Answer: None. Community Action Agencies have been required to complete an annual audit prior to the use of the Certification of Revenues and Expenditures statement for very small grants which were awarded for summer activities or one-time funding. The Certification procedure is not permitted in cases in which fraud or abuse are suspected, nor when there is not a history of sound fiscal management on the part of the grantee. It is not a good business practice to spend a large amount of Federal resources on auditing tiny grants particularly where the grantees have demonstrated fiscal integrity in the past. We believe the Congress did not intend to create a situation in which a significant percentage of a grant would be spent on an audit. The concern was to ensure adequate protection of Federal dollars. We have found this Certification procedure to be an efficient means of accounting for funds in instances where the Federal exposure is not great. The CSA/OCS Inspector General concurred in the use of this procedure for these modest amounts held by sound grantees.

EMERGENCY NEEDS

Question: Has OCS attempted to monitor or assist in any Community Services block grantee involvement in meeting emergency needs?

Answer: Emergency needs are a major focus of the Community Services Block Grant program. Under a technical assistance grant awarded to the National Governor's Association (NGA), the NGA has conducted a survey of States which found that CSBG operators in every State provide or arrange to provide some form of emergency shelter, food, clothing, or medical or related services. NGA also

found that in 22 States alone, emergency assistance was provided to more than a million people, accounting for one-fifth of the total CSBG allocation to those States.

OCS is now working to implement our portion of the emergency jobs legislation. All grants were awarded before April 30, 1983. We are also working closely with the Federal Emergency Management Agency (FEMA) to help them implement their part of the Jobs bill. In addition, we recently reached an agreement between DHHS and the Department of Defense on a Food Bank initiative. This agreement will allow food banks across the country to acquire non-marketable foodstuffs from military commissaries.

Question: What role does the Office of Community Services play in helping this Administration formulate policies designed to assist low-income citizens?

Answer: OCS participates in the Departmental processes of policy formulation. OCS makes recommendations based on its experience with administering the CSBG and will continue to do so.

OCS STAFFING

Question: On October 6, 1981, the Secretary published in the Federal Register a statement of organization, functions and delegations of authority for the Office of Community Services. For the record, could you provide this Committee with a review of how each division has been staffed and the progress to date you have made in making the Office of Community Services a true "Operating Division" within HHS?

Answer: OCS is staffed with 161 employees. Eighty-three (83) are in Headquarters. Seventy-eight (78) are Regional employees on detail to other positions because the Regional Office work has been completed. With the successful detailing of the Regional employees, we have been able to move some people within Headquarters. This is what our Headquarters staffing pattern looks like as of April 1, 1983.

Office of the Director - 14
Office of State and Project Assistance - 3
  Division of Block Grants - 11
  Division of Discretionary Grants - 5
Office of Special Grants Programs - 9
  Division of Grants Management - 10
  Division of Grants Administration - 11
Office of Management Services - 15
Office of Program Policy and Planning - 0 (Function handled in Office of the Director and the other offices).
Office of External Affairs - 2
Office of the Inspector General for the
  Office of Community Services - 0 (Function handled by HHS Inspector General).
Legal Advisory Staff - 3

CSBG FINDINGS

Question: Have you collected any data that you can share with this Committee concerning the type of clientele being served by CSBG grantees or perhaps can you tell us if local program operators have

changed their programmatic thrust in any way to meet the increased demands caused by the recession?

Answer: Our review of State plans indicated that most States intend to target CSBG services to individuals and/or families at or below the OMB poverty guidelines.

State applications for FY 1983 show that 83 percent of the States target CSBG services and assistance to people at or below the official poverty guidelines--$9,900 for a family of four. Another 4 percent make services and assistance available to the working poor--people whose incomes do not exceed 125 percent of the poverty level. Over 30 percent of the States target specific groups with special needs--such as the elderly or the unemployed--as an additional condition for eligibility.

The CSBG has been used by many States as part of an overall effort to meet human needs. The National Governor's Association conducted a survey to find out what States are doing to confront human emergencies, and found that CSBG operators in every State provide or arrange to provide some form of emergency shelter, food, clothing or medical and related services. Several States have used the flexibility inherent in the block grant to launch new initiatives that emphasize emergency assistance, often using the CSBG in conjunction with other programs that serve low-income people.

Question: Can you tell us if your Office of Program and Planning has conducted "program policies and planning strategies through analysis and evaluation of issues" that would help this Committee assess the CSBG funding needs for FY 1984?

Answer: In the Office of Community Services, policy development and planning has generally been developed and approved in the Office or Division where the issues were of concern. For example, the Office of Special Grants Programs was responsible for closeout of CSA grants and grantees. All policy related to grantee closeout was developed within this office. In the case of policy development and planning and analysis related to the CSBG, the Department was also involved in the policy development process because of its experience with the management of block grants.

IMPACT OF CSBG ON GRANTEES

Question: What has been the impact of the Community Services Block Grant and accompanying budget cuts on the nationwide network of Community Action Agencies?

Answer: As a result of our grant to the National Governor's Association, we have received information that shows that Community Action Agencies continue to be funded. NGA estimates that CAAs and other CSBG community-based and special purpose agencies administered more than $2.7 billion in Federal, State and locally funded programs in FY 1982. CSBG funds are used in conjunction with other Federal funds through programs for energy assistance, housing, aging, nutrition, Head Start, and employment training.

The change to block grants has helped the States target funds on the people who need them most. Under the former Community Services Administration, some States had one-quarter to one-half of

their territory unserved by CSA grantees; most of these States have moved to expand the program to these unserved counties. Also under CSA, some grantees with similar populations received very different levels of Federal support. The States have moved to establish more equitable formulas, usually based on the proportion of poor people in different parts of the State. As the States address these inequities, some local eligible entities will receive relatively larger amounts than they have in the past, and some will receive smaller amounts.

Question: Have any Community Action Agencies closed down as a result of the block grant and budget cuts?

Answer: We do not know the answer to this question since States are not required under the CSBG to report to OCS those organizations they fund. Even though the law requires States to use 90 percent of their allocations to make grants to eligible entities, the law does not require States to provide funds to every eligible entity within the State. We do know that Community Action Agencies and other eligible entities receive the majority of their funding from sources other than the CSBG. Therefore, if eligible entities have closed down since the implementation of the CSBG, it would be difficult to say that CSBG budget cuts directly caused any CAAs to close.

Question: To what extent have Community Action Agencies been kept alive by the provision of the 1981 Reconciliation Act that required States, during FY 1982, to use at least 90 percent of their block grant allotments for previous grantees of the Community Services Administration?

Answer: Most States would have continued to provide funds to existing eligible entities regardless of the 90 percent passthrough requirement. The National Governor's Association, in a survey of the Fiscal 1982 program, found that out of 37 States, more than half granted an amount greater than reuired to eligible entities. Twelve of the 37 States passed through 95 percent of their total CSBG allocations--retaining only the 5 percent allowed for State administration. One State, which spent only 3 percent for administration, passed through 97 percent.

Our analysis of State applications for FY 1983--which was prepared before the passthrough requirement was extended through the current fiscal year--showed that more than half of the States intended to provide funds to every eligible entity in their jurisdictions. Only seven States intended to fund political subdivisions exclusively, and several of these States would have used localities as a conduit to provide funds to eligible entities.

CSBG REPORTING

Question: Are the reporting and auditing requirements in the Community Services Block Grant legislation adequate to ensure proper use of Federal funds and to provide Congress and the Administration with information about how funds are being spent?

Answer: The Community Services Block Grant legislation requires audits every two years. Therefore, OCS has not yet re-

ceived audits of the funds provided to the States. We will be in a better position to determine the adequacy of this requirement once audits have been received for review. The State plans and expenditure reports provide information to aid in the Federal oversight of the program. Accountability is also promoted through the requirements for State legislative hearings through the membership of low-income people on the boards of the local grantee organizations, and through citizen participation at the local level.

OCS STAFFING

Question: What is the final status of the lawsuit filed against the Department of Health and Human Services by the former employees of the Community Services Administration?

Answer: There has been no final decision by the Judge in regard to this case. It is expected that there will not be any decision until the Merit Systems Protection Board has ruled.

Question: How many former Community Services Administration employees were hired as a result of this lawsuit?

Answer: When OCS was established in October, 1981, 240 people were hired to staff this office. As a matter of policy, the Director has requested that former CSA employees be hired wherever practicable wherever there are vacancies to be filled.

Question: Were these people hired in temporary or permanent jobs?

Answer: When OCS was established, 35 temporary employees were hired and 210 permanent employees were hired.

Question: How many employees do you have on board at the Office of Community Services?

Answer: OCS has 161 employees on board as of April 1, 1983.

Question: What has been the impact on State planning procedures of the extension through FY 1983 of the FY 1982 provision requiring States to use at least 90 percent of their block grant allotments for previous grantees of the Community Services Administration?

Answer: One of the reasons that the Administration opposed the 90 percent pass-through rule was that the States had spent months developing their programs in line with what they thought Congress had intended. With the passage of the First Continuing Resolution for FY 1983, the 90 percent pass-through requirement was extended, amending the law on the first day of the new fiscal year. The planning that the States had done therefore became irrelevant in many States.

The real disruption of State planning occurred because the Office of Community Services was unable to issue grant awards until the States assured in writing that they would comply with this pass-through requirement in FY 1983. Relatively few States are in a financial position to maintain the program for very long when Federal funds are delayed.

STATE PROGRAMS UNDER CSBG

Question: What had States planned to do with their Community Services Administration?

Answer: Nearly half of the States administer the CSBG through the offices which were the CSA counterpart offices at the State level. These State offices of Community Services and/or State Offices of Economic Development are experienced with community services programs and have played a major role in implementing the CSBG. Other States have administered the CSBG through other Departments or Divisions of the State government.

Question: What had States planned to do with their Community Services Block Grant in FY 1983, before the so-called grandfathering" provision was extended by the Continuing Resolution?

Answer: Our analysis of State CSBG applications for FY 1983 shows that the effect of the 90 percent pass-through requirement was negligible. At least half of the States intended to provide funds to every eligible entity from the very beginning. Other States had planned a mix of funding for eligible entities and political subdivisions, often because some subdivisions were not served by Community Action Agencies or other eligible entities. Only 7 States indicated they would provide funds only to political subdivisons, and these political subdivisions may have funded CAAs.

A negative effect of the pass-through requirement has been a reduction in State flexibility because States are unable to use CSBG funds to establish new community-based anti-poverty agencies, even in areas of the States that have never been served by a Community Action Agency. The initial legislation for the FY 1983 CSBG--before the continuation of the pass-through requirement--required States to "give special consideration in the designation of local Community Action Agencies to any Community Action Agency which is receiving funds under any Federal anti-poverty program" as of October 1, 1982. We believe this "special consideration" requirement provided ample assurance that States would not close CAAs on a widespread basis even without the 90 percent pass-through provision.

SUPPLEMENTAL JOBS BILL

In Fiscal 1982, funding was cut from $526 million to $348 million, when block grant legislation replaced services previously funded through the now defunct Community Services Administration. On the recent "Jobs" supplemental, an extra $25 million was appropriated, raising Fiscal 1983 to $373 million.

Question: How soon will these funds be distributed to the States?

Answer: Grant awards under the Supplemental Jobs Bill were made April 29, 1983. The $25 million appropriation will be distributed in one-time allocations to the States as supplements to their CSBG funds.

Question: What is your estimate of how much of these (Emergency Jobs Bill) resources States can actually spend by September 30, 1983?

Answer: As States revise their CSBG applications to reflect the use of the additional funding, we will receive copies of those revisions. The information will then be available.

OCS staff have been working closely with the States in question concerning the emergency jobs legislation. States are already spending a considerable portion--about one-fifth--of their CSBG funds on emergency services. We believe the States will follow the stated intent of Congress and spend these funds as expeditiously as possible in ways that address the problem of unemployment.

Questions Submitted by Senator Mark Andrews

DISCRETIONARY GRANTS

Question: I understand that in FY 1982 applications were funded that did not rank as high as others not funded. Please describe the process followed last year and the process to be followed in FY 1983.

Answer: As a result of the announcement published last year in the Federal Register, OCS received over 500 applications for grants from the discretionary program. Each of these applications was fully reviewed by outside reviewers. Applicants that did not meet technical requirements, such as the need for a matching share, were not approved for funding, even though the programmatic merits of their proposal may have been rated highly. Therefore, a proposal that may have been highly rated for programmatic reasons in the review process, but which failed to meet the technical requirements of the program, would not have been funded. The program announcement published for the FY 1983 discretionary program gives careful and specific direction which shall make it easy for applicants and reviewers to be responsive to the program requirements. The specifics in the program announcement should minimize any problems in the applications which are submitted in meeting the technical requirements for the program.

Question: The history of the OEO/CSA program has been one of providing grants to local community based non-profit organizations. I understand that the RFP issued March 23, 1983 for the discretionary fund makes for-profit organizations eligible for grants. What is the rationale for this?

Answer: It is Department policy as stated in the Federal Register that for-profit organizations will be eligible grantees of DHHS programs. OCS has concluded that this policy applies to the discretionary grants program as it does to other DHHS grants programs. This policy was formulated to increase competition so as to ensure the best performance in programs in which performance of an activity or project, rather than institutional support, is the goal of the program. Federal regulations provide that no grant funds may be paid as profit to any recipient of a grant or sub-grant even if the recipient is a for-profit organization.

Question: Where in the legislative history of this program or its predecessors do you find the basis for this action?

Answer: The CSBG discretionary grants program provides funding for one year to support project activities that will result in direct benefits to low-income people. It is not a program of institutional support, as were many of the programs conducted by CSA and OEO, and which were funded under different legislative authority which has expired. OCS is following the established policy of the Department of Health and Human Services in opening this grants competition.

Question: Do you have a plan for recapture or control of profits of for-profit organizations receiving grant funds under the discretionary fund?

Answer: No grantee organization of this program, whether for-profit or non-profit, can use grant funds provided for its own enrichment and no grant funds may be paid as profit to any recipient of any grant or subgrant from this program. Use of grant funds is restricted to allowable costs of the approved work program of the grantee.

Question: Are there any requirements for minority hiring?

Answer: There are no requiements for minority hiring. However, organizations supported with grant funds are required to follow applicable State and Federal regulations related to minority employment.

Question: The RFP notes that applications for use with enterprise zones are encouraged. As there is no Federal legislation for enterprise zones, how do you intend to define enterprise zones?

Answer: The announcement published in the Federal Register encourages applications that are linked with enterprise zone initiatives. Enterprise zones are defined as "..a geographic urban neighborhood or rural community of high unemployment and pervasive poverty..in which a legislative entity has enacted a program or tax and regulatory relief to encourage business development." Sixteen States have enacted enterprise zone legislation while legislation is pending in 14 additional States. At the present time 225 areas have been designated as enterprise zones.

Question: Will only States with State passed enterprise zone legislation be eligible?

Answer: No. The encouragement of proposals related to enterprise zones is only one example of emphasis within the overall program priority area of Urban and Rural Community Economic Development. OCS expects that most applications in this funding category will not relate to specific enterprise zones.

Question: How will organizations from States with no State enterprise zone legislation participate in such a demonstration program?

Answer: As noted in the previous answer, enterprise zones are not exclusive in the grants competition. The invitation for these

applications is a part of the overall solicitation for proposals in urban and rural community economic development. All applications for funding within this program priority area will be reviewed on the merits of their proposed impact on low-income people and for their responsiveness to the program announcement. Applicants not located in enterprise zone areas are welcome to propose economic development activities that are responsive to the announcement.

Question: Can you define more precisely 'administrative costs' found in the RFP?

Answer: For the purpose of the FY 1983 announcement, administrative costs are taken to be those costs necessary to properly protect, monitor, account for and apply to the approved project those Federal funds awarded. Costs associated with the internal operational management of the approved project are not considered to be administrative costs for the purposes of this announcement.

Question: Also, in cases in which an applicant has an HHS approved indirect cost rate, will that be acceptable to HHS?

Answer: In all cases where an applicant has and claims an HHS approved indirect cost rate, this rate will be recognized by OCS, and applied to any OCS award. It is emphasized that such indirect costs are part of, and not in any way additional to, the amount awarded to a grantee. In most cases, indirect costs will include not only many administrative costs, but also many other allowable costs, and thus the approved cost rate may often exceed the 10% limit on administrative costs.

Questions Submitted by Senator Alfonse M. D'Amato

COMMUNITY DEVELOPMENT CREDIT UNIONS

Question: It has been seventeen months since this Committee and the Congress first gave the Department direction regarding obligation of Credit Union Revolving Loan Fund balances. During that time the National Federation of Community Development Credit Unions has offered and has been requested by OCS to provide substantial assistance to the Department - at great expense to the Federation, I might add - regarding the CULF. Yet in all that time and in spite of all of the good faith efforts by my office and the Federation, not one loan to a credit union has been made. Can you give me any reasonable explanation why no CULF loans have yet been made?

Answer: Secretary Schweiker committed last April to fund the Community Development Credit Union (CDCU) program with $1.6 million by the end of FY 1982. OCS went ahead with drafting the regulations and program announcement to meet this goal. Concurrently, the OCS Inspector General's Office was conducting a study of the CDCU, including site-visits to 6 of the 28 recipient credit unions. In June it was discovered that substantive revisions to the regulations were going to be needed--most notably regarding the interest rate to be charged to the participating credit unions. The previous regulations had placed a 2% interest ceiling on the loans to CDCU's, and this rate was considered too low in light of the prevailing

interest rates in the economy. Thus new regulations would be needed to be published for a comment period. In July it was discovered that there were sizeable delinquency problems with the loans to CDCU's: 20 of the 28 CDCU's were delinquent for a total of $197,000. In September the IG issued his reports on the CDCU program, finding defective administrative procedures in the program. Taking into consideration the IG reports, the delinquency problem, and the interest rate ceiling, OCS re-drafted the regulations and program announcement. The National Credit Union Administration (NCUA) was brought into discussions, since the program was under jointly issued regulations between CSA and NCUA. The NCUA Board of Directors decided at its January meeting that it would prefer OCS itself to issue the regulations for comment. Therefore, in early February OCS submitted its draft regulations to HHS for internal comment. These comments have been received. The revised regulation has been submitted to HHS and to OMB for publication in the Federal Register.

Question: It is my understanding that you have requested an apportionment from OMB for CULF loans, not loan guarantees. Is that correct? Has OMB granted or do you expect them to grant a CULF apportionment for FY '83 loans in the amount equal to the entire remaining balance of the CULF?

Answer: The Department did request an apportionment for loans (and loan guarantees) from OMB for this program in July, 1982; it was returned without action pending completion of changes in regulations. We are currently revising these regulations and will submit them to OMB for review once they are completed. Once approved, we will submit an apportionment for the remaining balance in the account to OMB.

Question: Do you expect to publish a CULF regulation and/or a request for loan applications within the next 30 days? Do you expect to be able to obligate all available funds in FY 1983?

Answer: OCS expects to publish a regulation in the Federal Register during May. Allowing for a 30-day comment period and subsequent revisions, we plan to be able to publish a final rule in July. Applications would be received in August and September. It is hoped that awards may be made before the end of the fiscal year. These funds remain available until expended.

Question: How do you plan to implement the Congressional requirement to ensure the availability of appropriate management and technical assistance to CULF recipients? Will you provide that assistance directly? If so, how? Will you contract for or make a grant for such assistance? Can you contract for or make a grant for such assistance from the $12.5 million OCS administrative account? Did you turn back FY '82 funds to the Treasury from the OCS administrative account?

Answer: We will shortly be publishing the revised CULF regulations in the Federal Register. We look forward to the comments that will be received following publication to assist us in finding the best solution to management and technical assistance problems. We have also discussed technical assistance needs with the National Credit Union Administration (NCUA). Based on all of these comments, OCS will assess the requirement for technical assistance and the ability of this office to provide technical assistance. If neces-

sary, we will explore the making of an expenditure from the administrative account for this purpose. There were administrative funds returned to the Treasury in FY 1982 because positions authorized exceeded the actual staffing of the newly created Office of Community Services.

Questions Submitted by Senator William Proxmire

AMENDMENT TO SOCIAL SERVICES BLOCK GRANT

Question: Ms. Hardy, on page two of your prepared testimony you state "An amendment to the Social Service's Block Grant will be proposed to allow States to carry out most activities previously carried out under the Community Services Block Grant."

Since no language on this subject is contained in your justifications, I assume that this language will be submitted to the authorizing committee, is that correct?

Answer: Yes, we will be submitting an amendment to the Social Services Block Grant to the authorizing committee.

Question: When will the language in question be submitted?

Answer: The language in question has been under review at the Office of Management and Budget. It was submitted to the authorizing committee on April 27, 1983.

HEAD START

Question: Can you tell us how average class size has changed over the last five years?

Answer: Firm figures on average class size in Head Start are available for the past three years, and we have estimates for prior years. For fiscal years 1978 and 1979, average class size was estimated at 18 children per class. By fiscal year 1980, average class size had risen to 20.4. In fiscal year 1982 we show an average class size of 18.2.

Question: How much has the average staff salary increased over the past five years?

Answer: We do not have figures which would enable us to derive an average for all Head Start grantee staff over the past five years, but we do have data on teachers' salaries, which we have used in recent years as a proxy for all staff salaries. The average teacher salary in fiscal year 1978 was $5,600 per year; in fiscal year 1979 it was $6,000; in fiscal year 1980 it was $6,865. Teacher salaries in fiscal year 1981 are estimated to have risen to $7,728; in fiscal year 1982 the estimate is $8,700. Over this period the average staff salary has increased by 55 percent.

PROGRAM INCOME

Question: Your recent emphasis in administering aging programs has been to increase voluntary program income according to the narrative on page 39 of your justifications. How much has this income increased over the past few years?

Answer: During the past few years States have reported the following amounts in program income expenditures:

FY 1980	FY 1981	FY 1982
$67,000,000	$78,900,000	$100,900,000

ADMINISTRATION ON AGING - SUPPORTIVE SERVICES AND SENIOR CENTERS

Question: Your justification narrative, in discussing your Supportive Services and Senior Centers budget request, states: "Area agencies must give special emphasis to the provision of services to socially- or economically-needy older persons." How do you determine whether or not an older person is socially-needy?

Answer: Section 305(a)(E) of the Older Americans Act mandates that the State agency provide assurances that preference will be given to providing services to older individuals with the greatest economic or social need. Section 1321.3 of the regulations published by the Administration on Aging pertaining to Title III of the Act, defines greatest social need as: "the need caused by non-economic factors which include physical and mental disabilities, language barriers, cultural or social isolation including that caused by racial or ethnic status (for example Black, Hispanic, American Indian and Asian American) which restrict an individual's ability to perform daily tasks or which threaten his or her capacity to live independently."

Question: What criteria do you use in determining whether or not an area agency is giving special emphasis to serving the economically- or socially-needy?

Answer: State agencies must conduct periodic assessments of the activities performed by area agencies. Part of these assessments include an examination of how the area agency is providing the required emphasis on serving the economically- or socially-needy elderly.

At the Federal level, there is no assessment of area agency activities. However, program data reported by the States at the end of fiscal Year 1982 reflect that of the recipients of Supportive Services, 44% were socially-needy older persons and 52% were economically-needy older persons. The same data reflect that, of the recipients of Congregate Nutrition Services, 50% were socially-needy older persons and 67% were economically-needy older persons. Finally, 54% of the recipients of Home-delivered Nutrition Services were socially-needy older persons and 67% were economically-needy older persons.

AWARDS TO TRIBAL ORGANIZATIONS

Question: I note that awards made to tribal organizations under the Older Americans Act can be used for road clearing. Can you tell us what the rationale is for this use of the funds and how much money was spent for this purpose in each of the last three fiscal years?

Answer: The purpose of Title VI of the Older Americans Act is to provide services to older Indians which are comparable to services under Title III. Access is one of the services funded under Title III. The regulations published by the Administration on Aging pertaining to Title VI of the Act specify road clearing as an example of those services which facilitate access and which may be provided under the grant. Many older Indians reside in isolated sections of the reservation, where accessibility to services is particularly affected in the winter months. Road clearing was included as an example of permissible access services in response to this need.

Road clearing services is only one of the many services which can be provided by a grantee. We do not have information on the funds which are used in providing this service.

DISCRETIONARY FUNDING

Question: Can you tell me how much money the Office of Human Development Services will spend on research in fiscal year 1983 and fiscal year 1984?

Answer: The Office of Human Development Services expects to spend up to $24,951,000 in Fiscal Year 1983, and an estimated $10,869,950 in Fiscal Year 1984. It is anticipated in FY 1983 up to 98.3% of our research dollars will be used in connection with applied and developmental research activities including demonstrations intended to test or refine technologies and methods by which to improve the operating efficiencies of human service delivery systems, examine effective means of targeting HDS program resources, and increase the service related involvement of family and community based resources.

Question: A task force report of the President's Private Sector Survey on cost control has this to say about your research expenditures.

"The cost of the HDS investment in social research may exceed the benefits. Research results cannot be directly associated with program, policy, or legislative changes. Also, most HDS programs are mature and should not require significant research funding to sustain established levels of service. Yet research studies continue to be funded in areas that have been heavily researched in the past, so that the incremental contribution of such expenditures is questionable."

"Current research dissemination and usage strategies assume a need for the research product, but may indicate a lack of critical demand for research results. The target audience that will receive and use research results is often not identified before studies are funded." What is your response to these criticisms?

Answer: The task force report of the President's Private Sector Survey was just recently made available to the Office of Human Development Services. We are currently reviewing the report and will make use of the findings in our FY 1984 planning activities. I would add, however, that in FY 1984 the Administration has proposed a significant reduction to the level of discretionary funds available. As in FY 1983, these funds will be used in connection with major developments of high interest and priority to State and local human service agencies.

SUPPORT FOR INDIAN PROGRAMS

Question: I note that your program of financial assistance grants to Native Americans will provide somewhat increased support to Federally recognized Native Americans in fiscal year 1984 but will substantially reduce support for non-federally recognized Native Americans especially in urban areas. Does this reflect the fact that the Bureau of Indian Affairs, which has little familiarity with urban problems, would have been administering the program, or is there some other reason?

Answer: The funding level for Federally-recognized tribes for fiscal year 1984 is relatively the same as the levels in fiscal years 1982 and 1983. The reduced level for non-federally recognized groups reflects the fact that these groups will be phased-out over a three year period beginning in fiscal year 1984. The phase-out is not related to the transfer of the administration of grants to Federally-recognized tribes through the Bureau of Indian Affairs. The reduced funding level for non-federally recognized groups is related to the fact that these groups fall within the jurisdiction of state and local governments and are eligible to be served through block grants and categorical programs to states, and discretionary programs to state or local governments. Furthermore, current ANA funded projects to non-federally recognized groups are expected to accomplish results that are lasting and do not require ongoing Federal support. The phase-out will be gradual as these groups will continue to be eligible for ANA funding in fiscal years 1984 and 1985.

FOSTER CARE

Question: The administration is placing a strong emphasis on placing foster care children in permanent adoptive homes. How many foster care children have been located in adoptive homes over the past two years?

Answer: Data describing the number of children adopted annually from foster care are not available at the time. However,

we do have data on a small part of the total picture, children receiving adoption assistance with Federal financial participation under Title IV-E of the Social Security Act. The Title IV-E Adoption Assistance Program began slowly in Fiscal Year 1981, with only a few States able to adopt the new procedures needed to implement the Program. The average monthly number of children provided adoption assistance with Federal financial participation has increased from slightly under 300 in Fiscal Year 1981 to just over 1300 in Fiscal Year 1982 to an estimated 3000 to 4000 in Fiscal Year 1983.

DISCRETIONARY FUNDS

Question: The Office of Human Development Services (OHDS) has recently begun to coordinate the award of discretionary funds in the human services area, using funds from several OHDS program components. Does the Commissioner on Aging retain the right to make final decisions on the award of the Administration on Aging's (AoA) discretionary funds?

Answer: The Commissioner on Aging approves the use of all funds under Title IV of the Older Americans Act, including funds for projects resulting from the combined Office of Human Development Services announcement. Staff review not only those proposals resulting from the combined announcement which specifically address the problems and needs of older persons, but those proposals which are cross-cutting (that is, covering more than one Human Development Services target group) to insure that older Americans will benefit from the grant. For proposals which concern management techniques in social services, for example, service providers for all target groups are likely to gain.

After such proposals are funded, an Administration on Aging staff person serves as the project officer for the grant or cooperative agreement if Title IV provides the sole source of funds, or a substantial portion of the funds used. For grants where the Administration on Aging provides a smaller portion of the funding, we provide a co-project officer who must approve all changes in the grant.

The Commissioner, through Administration on Aging staff, closely monitors all grants and cooperative agreements to insure that the projects fulfill their stated goals. In many cases, older people gain from cross-cutting grants because they bring additional resources to bear on the needs and problems of the elderly.

Not only does the Commissioner make the final decisions on proposals to be funded by the Administration on Aging, but the Commissioner, after considerable consultation with experts in the field of aging, developed a series of priorities and recommendations for inclusion in the combined announcement.

Question: How are the AoA funds apportioned to projects which also receive funds from other Office of Human Development Services components?

Answer: The Administration on Aging's contribution for projects which also receive funds from other Office of Human Development Services components is based on the amount of the project oriented to an individual target group.

The Administration on Aging has funded to date, 42 grants resulting from the 1982 combined announcement; 18 were jointly funded with other components of the Office of Human Development Services, and 24 were funded solely by the Administration on Aging. Total Title IV funding to date under the combined announcement is $6,953,647; of this amount $5,627,040 supported grants solely funded by the Administration on Aging, and the balance, $1,326,607, supported jointly-funded projects.

Question: What would be the outcome if the Commissioner on Aging disagreed with recommendations made by the Office of Human Development Services on whether, and to whom, to make an award of funds?

Answer: Final funding decisions are based on panel ranking as a primary criterion. In addition, factors such as geographic distribution, participation of minorities, and recommendations by Administration on Aging staff were taken into account by the Commissioner on Aging and the Assistant Secretary for Human Development Services in making the decisions. The Commissioner on Aging approves the use of all funds under Title IV of the Older Americans Act.

UNOBLIGATED BALANCES LAPSING

Question: In fiscal year 1982 the Human Development Services appropriation lapsed $9,908,000. For the record tell us what programs and activities lapsed funds and why the funds could not be spent?

Answer: The following Human Development Services programs lapsed funds in fiscal year 1982:

Head Start	$3,060,000
Administration on Aging	1,047,000
Administration for Developmental Disabilities	427,000
Administration for Native Americans	43,000
Prior year balances not available	848,000
Net transfer from "M" account-not available	300,000
Deobligation reimbursement	51,000
Total.....	$9,908,000

There are several reasons why these funds could not be spent. In the case of Head Start, carryover balances must be used prior to new funds. In some instances, the actual cost of some grants and contracts was less than initial estimates. These findings occurred too late in the fiscal year to effectively reallocate funds. In the case of salaries and expenses, the pay raise supplemental was received late in the fiscal year. In addition, the actual cost of implementing the reduction in force was less than originally estimated. In other

cases, approval of discretionary grant awards did not occur in time to obligate funds prior to the end of the fiscal year.

Question: In fiscal year 1982 the Child Welfare appropriation lapsed $5,903,000. For the record tell us what program and activities lapsed funds and why the funds could not be spent?

Answer: The following Child Welfare programs lapsed funds in fiscal year 1982:

Foster Care	$2,784,000
Adoption Assistance	3,119,000
Total.....	$5,903,000

These programs are full entitlement programs. Claims submitted and approved were less than the funding level made available.

RATIONALE FOR SLUC ESTIMATES

Question: You are anticipating an increase of almost 50 percent in your rental fees under the Standard Level Users Charges (SLUC) program administered by the General Services Administration. Your SLUC charges would jump from $3,565,000 this year to $5,225,000 in fiscal year 1984. Can you tell us why this is occuring in the face of a staffing decline of 11.6 percent?

Answer: The General Services Administration has indicated that SLUC charges for 1983 will be the same as for 1982. Our initial estimate for 1983 was considerably higher. The estimate for 1984 reflects our best estimate of actual charges.

Questions Submitted by Senator Daniel K. Inouye

NATIVE HAWAIIANS

Question: The Administration has indicated that it plans to totally phase out all support for non-federally recognized tribes and Native American organizations. The Office of Human Development Services has a good track record of actively supporting efforts in the State of Hawaii to address the unique and pressing economic and social needs of Native Hawaiians. Accordingly, the Committee would appreciate learning the extent of support during this Fiscal Year for native Hawaiian organizations and peoples, as well as comparable figures for FY 1982?

Answer: During fiscal year 1983, the Administration for Native Americans (ANA) will fund two grantees for a total of $1,177,726. In fiscal year 1982, ANA funded two grantees for $1,150,321.

Question: Whether any of the Native Hawaiian organizations are eligible for becoming "federally recognized" and whether those Native Hawaiians residing on Hawaiian Homestead lands should be considered as if they were American Indians residing on Indian reservations?

Answer: The responsibility for determining eligibility for Federal recognition rests with the Department of the Interior. To the best of our knowledge, there are no Native Hawaiian organizations that meet the criteria for Federal recognition established by the Secretary of the Interior. It is our position that Native Hawaiians residing on Homestead lands are not the same as Indians residing on Indian reservations for purposes of the FY 1984 budget request. We believe that ANA's primary role should be to assist in strengthening those tribes for which the Federal government has a clear and recognized relationship.

Question: Whether there are any federal agencies which would "fill the void" if the Office of Native American programs were no longer to serve Native Hawaiians?

Answer: Current ANA funded projects to Native Hawaiian groups are expected to accomplish results that are lasting and do not require ongoing Federal support. Communities served through these projects fall within the jurisdiction of State and local governments.

Question: What data the Department possesses which suggests that Native Hawaiians no longer need active federal support of the type that they have received from the Office of Native American programs?

Answer: The proposed phase-out of grants to Native Hawaiian organizations is not based upon a specific study or any particular data. It is our belief that the ANA funded projects will accomplish results that are lasting and do not require ongoing Federal support. The phase-out will be gradual as Native Hawaiian organizations will continue to be eligible for ANA funding in fiscal years 1984 and 1985, and are also eligible to be served through block grants and categorical programs to states, and discretionary programs to state or local governments.

SUBCOMMITTEE RECESS

Senator WEICKER. The subcommittee will stand in recess until tomorrow morning at 9:15 when we will start on 2 days of hearings relative to the National Institutes of Health.

Thank you very much.

[Whereupon at 9:25 a.m., Monday, April 11, the subcommittee was recessed, to reconvene at 9:15 a.m., Tuesday, April 12.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1984

TUESDAY, APRIL 12, 1983

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, D.C.

The subcommittee met at 9:15 a.m., in room SD–116, Dirksen Senate Office Building, Hon. Lowell P. Weicker, Jr. (chairman) presiding.

Present: Senator Weicker.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

STATEMENT OF DR. JAMES B. WYNGAARDEN, DIRECTOR

ACCOMPANIED BY:

NORMAN MANSFIELD, DIRECTOR, DIVISION OF FINANCIAL MANAGEMENT

DR. WILLIAM RAUB, DEPUTY DIRECTOR FOR EXTRAMURAL RESEARCH AND TRAINING

ANTHONY ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET, HHS

OPENING STATEMENT

Senator WEICKER. Good morning. The hearing will come to order.

Today we will hear from the National Institutes of Health in support of its fiscal 1984 budget.

The work carried out by NIH represents humanity's hope for conquering the diseases which bring pain and suffering to so many in the world. One measure of how well NIH has performed its mission is the fact that it has supported the work of 85 Nobel-Prize winning scientists.

However, it is clear that the proposed fiscal 1984 budget does not do justice to NIH. The actual increase is only $73 million above the fiscal 1983 level, meaning that under such an approach, the Institutes would have far less than they need to continue the current level of activity into the new fiscal year.

Morever, the proposed increase is less than 2 percent above the fiscal 1983 level at a time when forecasts put price inflation for biomedical research at between 5.3 percent and 5.5 percent for fiscal 1984.

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The administration belatedly has decided to change its January budget submission so as to fund 5,000 new and competing research grants. Before anyone gets too excited about that development, you should know that the grants will be at less than full cost. And the revised budget does not provide the additional funds to pay for the increase of 1,324 grants above the 3,676 requested in the January budget.

Instead, the budget revision proposes to take away $140.9 million from other NIH activities in order to bring the total number of new research grants to the 5,000 level.

As a result, there will be in some fashion as far as the administration's budget is concerned, major cuts in continuation and discretionary grants, in research centers, and in applied research, among other areas.

Also, the revised budget proposes to defund the Gorgas Memorial Institute which conducts research on tropical diseases through its laboratory in Panama. The Institute was named after Dr. William Gorgas, the man who conquered yellow fever.

Here to testify on the revised NIH budget for fiscal 1984 is Dr. James Wyngaarden, the new Director of NIH, who is making his first appearance before this subcommittee.

Dr. Wyngaarden, we welcome you and your staff to our hearings. You may proceed to make the presentation in any way that you deem fit.

You might, prior to that, introduce your colleagues who accompany you at the table.

INTRODUCTION OF ASSOCIATES

Dr. WYNGAARDEN. Thank you very much, Mr. Chairman. With me today are Mr. Norman Mansfield, Director, Division of Financial Management; and Dr. William Raub, Deputy Director for Extramural Research and Training.

BUDGET REQUEST

I appreciate this opportunity to speak on behalf of the President's proposed 1984 budget for the NIH and to report on the state of the national biomedical research enterprise.

As you mentioned, this is my first appearance before your subcommittee. I became Director last spring when the budgetary process was already underway. I look forward to working with you and other members of the subcommittee as we chart the course for continued progress in biomedical research.

In speaking of NIH and its programs, as you know, we are referring to a nationwide collaborative research network that has been created by a multibillion-dollar public investment over the past 30 years. This network currently involves some 45,000 scientists and 1,200 institutions throughout the country.

The primary objective of this partnership with government is to generate fundamental biomedical knowledge and ultimately to apply it in the prevention, treatment, and cure of disease and disability. We believe

that we are on the threshold of greater health advances today than ever before, but we do have a long way to go.

Many of the essential pieces of fundamental information have yet to be discovered, but today's technology does enable us to pursue a rational course toward greater understanding and new methods for the prevention and treatment of disease.

This continued progress requires that we maintain the momentum of discovery even though the national economy demands restraint on Federal spending. Significant health benefits continue to flow regularly from the research enterprise as a whole. And in their testimony this morning, Mr. Chairman, the Institute Directors will detail some of these recent advances.

The pursuit of basic knowledge by many investigators, following their own curiosities, insights, and wisdoms, is what powers American research, and Federal support is the essential element in the success we enjoy.

STABILIZATION IN RESEARCH PROJECT GRANTS

Since 1973, NIH appropriations in terms of constant dollars have remained relatively level. Within that context, we have sought to emphasize stability in research project grants. Accordingly, NIH has increased the share of its total appropriation devoted to research project grants from 38.5 percent in 1977 to over 51 percent in the 1983 budget.

As a result, despite inflation, we have been able to maintain level support for new and competing research project grants. For example, in each of the last 3 years, we have supported between 4,900 and 5,100 new and competing research project grants out of a total research project grant portfolio that has averaged about 16,300 projects.

As you pointed out, the fiscal year 1984 budget will support 5,000 new and competing research project grants. To fund the 5,000 grants, we will again conduct downward negotiations in noncompeting grants and make reductions from study-section-recommended costs for new and competing grants.

FUNDING POLICIES

We will fund most other mechanisms at approximately the 1983 level. Two exceptions are the research centers program and biomedical research support grants where the proposed funding levels are below those of 1983.

We also intend to reduce indirect cost reimbursement to grantee institutions. The level, as a percentage of total research grant costs, increased from 20.6 percent in 1972 to about 30 percent in 1982. NIH believes that its expenditures for indirect costs should be adjusted downward as has been done with direct costs. The 1984 request assumes total indirect cost reductions of about $72 million.

As directed by the Appropriations Committee, we have carefully reviewed indirect costs and consulted with universities and other research organizations most directly affected. We have completed a report that

contains conclusions and recommendations for discussion, which I understand has just been submitted to the subcommittee.

As for our other priorities, we continue to emphasize research training. The fiscal 1984 budget will support 9,076 research trainees.

I should also mention that the budget includes $5 million for five major clinical trials. They include additional research into the acquired immune deficiency syndrome and the Kaposi's sarcoma problem, evaluation of biological response modifiers, studies of monoclonal antibodies as carriers of toxins, development of standards for initiation of kidney dialysis, and development of a vaccine for herpes simplex virus.

That concludes my summary statement, Mr. Chairman. I would be pleased to answer any questions you or the subcommittee members may have.

REVISED BUDGET REQUEST

Senator WEICKER. Dr. Wyngaarden, although the administration's 1984 budget was sent to Congress in January, late last week, we were informed that you were sending up a revised request for NIH.

In a February 2 letter to Chairman Hatfield, then Secretary Schweiker said that the administration intended to fund 5,000 new research grants, and all that remained was to make the necessary budget adjustments to achieve that policy.

The question on that is: What took so long? And to what extent did the former Secretary hope to get a budget increase to fund the 5,000 grants?

Dr. WYNGAARDEN. The initial submission in January was based upon a budget that had been developed over a 15-month period and revised to take into consideration the additional commitments that resulted from the continuing resolution passed in December.

At that time, we had not worked out the possible shift to fund a larger number of grants. Negotiations continued during the ensuing months between the Department and OMB.

We received the decision in late March that the administration commitment to 5,000 grants would be worked out within the existing budget; therefore, the budget was revised and resubmitted to you.

Senator WEICKER. The revised budget brings you to the level of 5,000 new research grants at an additional cost of $140.9 million. This added funding is put together not by increasing the NIH budget, but by cutting other NIH activities, including research centers, applied research, flexible research funding and other areas.

Do you regard this as a good trade-off for biomedical science, or do you have some reservations about it?

Dr. WYNGAARDEN. We feel that the highest priority in our total portfolio is the research project grant mechanism. It is the individual investigator-initiated research grant or project, whether conducted intramurally or extramurally, that gives rise to the basic new ideas in biomedical science on which progress rests.

This is not to say that the centers and the other mechanisms of support to which you refer are not also extremely valuable. But under a constrained budget, we have given highest priorities to those activities of NIH support that we consider the most central and fundamental to our mission—namely, the generation of new knowledge and biomedical science.

There is no question that the other mechanisms are valuable in translating research developments into the clinical arena and accelerating their relevance and transfer into medical practice; nevertheless, we still will be supporting a very large number of such centers and maintaining some flexibility for the research institutions under the President's budget.

IMPACT OF DOWNWARD NEGOTIATIONS

Senator WEICKER. The revised NIH budget provides an additional $140.9 million to increase the number of new research grants from the 3,676 requested in January to the 5,000 grants that are considered the stability level for the Institutes, a difference of 1,324 grants.

We are advised that the full cost of the 1,324 grants is $184 million rather than $140.9 million you now have requested. What will be the impact of not providing for the full cost of these grants and for the full cost of the 3,676 other new grants in your budget?

Dr. WYNGAARDEN. These new and competing grants will be negotiated downward somewhat more than in 1983, although we have been conducting downward negotiations for the last several years in order to fund approximately 5,000 new and competing grants each year.

The proposal for 1984 assumes a smaller growth in the size of new and competing awards and continuing awards than has been present in previous years—this year about 2.8 percent growth in new and competing, and about 3.6 percent in noncompeting—and assumes some other mechanism shifts, a savings that will enable us to support about 1,300 additional grants to reach the 5,000 level.

Senator WEICKER. We are advised it could cost as much as $385 million more than requested in your January NIH budget to do the same things in fiscal 1984 that you were funded to do in fiscal 1983. And since your revised budget doesn't change the total requested, doesn't that mean that you still would need far more than you request simply to keep running in place?

Dr. WYNGAARDEN. The President's budget assumes the savings that you have implied. We have been negotiating downward in several areas, and we have maintained most of the mechanisms at the 1983 level.

We believe that the President's budget provides a base for a very vital and vigorous research effort during 1984 even though it does include some reductions in other mechanisms as you have pointed out.

IMPACT IN OUT YEARS

Senator WEICKER. Well, let's see if we can sort of tackle this general area.

I gather no claim is made at this particular hearing as has been the case in previous hearings that the local and State governments and volunteers are going to take up the slack insofar as NIH is concerned. We can do away with that claim, or do we have to deal with it?

Dr. WYNGAARDEN. I am not claiming that, sir.

Senator WEICKER. So that leaves us really at a situation where—let's use the most optimistic projection of inflation in the biomedical area, or 5.3 percent. Therefore, in effect, that represents a reduction in addition to whatever reduction the administration has proposed.

Aside from the rhetoric and aside from the numbers, it would seem to me that considerable activities are going to be impacted here in terms of the funding.

Let me say this also, Dr. Wyngaarden, that I am sure if there are financial concerns, budgetary concerns, I will let Mr. Itteilag here propound the administration position, but you are not an economist, and whether or not you are a politician, I will allow that evaluation to proceed from yourself, not me.

But I am not asking you, in other words, to extend an economic program or where the priorities ought to be. I am only asking for your commentary in your area of expertise, that which you have responsibility for.

At least to my layman's knowledge, which is all I profess, certainly the area that you are concerned with is enormously expensive at any time under any set of circumstances. This stuff doesn't come cheap; it never has, and never will.

I suppose what I am really asking is that in all these activities, it seems to me that the investments are not being made right now which are so necessary to success in the out years. That's my real concern. Not that it doesn't show that the status quo—it probably does that, although we could argue as to whether it is going back by virtue of inflation, et cetera—but what is the cost going to be in the out years.

That is really the question that applies to so much of what you have laid out here before the committee.

Dr. WYNGAARDEN. We agree with those evaluations entirely, and it is precisely on the basis of that kind of evaluation that we have given research project grants the highest priorities within the President's budget.

Senator WEICKER. But even there, the research project grant isn't what it is today. It is going to be pulled down.

Dr. WYNGAARDEN. Only slightly.

MOMENTUM OF DISCOVERY

Senator WEICKER. Well, OK, but only slightly. I mean, do you feel you are going to get the same or more from the lower figure? If that is to be the policy of the administration, I suppose what I am saying is I am not so much interested in a 5,000 figure for rhetorical purposes.

Maybe then we ought to arrive at a lower figure and make sure that it is done right. I suppose that is really the point if we are going to have a head-on here between the committee and the administration.

Dr. WYNGAARDEN. Our policies of approximately the last 10 years have progressively shifted funds within essentially a constant budget into the research project category to maintain the momentum of discovery that you and we are concerned about.

It is indeed the work that is being done today that forms the basis for breakthroughs 10 or 20 years from now. Today, we are capitalizing on research in molecular biology, antibody research, that rests on investments made 10 and 20 years ago. It is that momentum of discovery that we are critically concerned with maintaining and supporting.

The NIH budgetary shifts of the last decade have reflected that philosophy. We have increased the percentage of the NIH budget that has been going to investigator-initiated research annually since 1974. The portion of the total NIH extramural portfolio that has been devoted to research grants of all kinds has increased from about 62 percent a decade ago to 83 percent last year.

It is precisely to maintain that momentum of discovery that those shifts have been made. However, within a budget that is constrained by the general economy, there are priority decisions that we must make. This is just such a year of priority decisions that have shifted funds from other mechanisms into research grants to maintain the momentum of which you speak.

Senator WEICKER. What if I could find you funds not within your own structure, but from without? In other words, the same paring of the budget, allocating the ever-shifting dollar within your budget, is not going on in some other budgets at the present time.

Dr. WYNGAARDEN. We are not asking for additional funds, Mr. Chairman.

CLINICAL TRIALS

Senator WEICKER. For example, I notice in the last paragraph in your formal statement you state:

> I should also mention that the budget includes $5 million for five major new high-priority clinical trials. They include additional research into the acquired immune deficiency syndrome and the Kaposi's sarcoma problem, evaluation of biological response modifiers, studies of monoclonal antibodies as carriers of toxins, development of standards for initiation of kidney dialysis, and development of a vaccine for herpes simplex virus.

Dr. WYNGAARDEN. Yes; that is correct.

Senator WEICKER. Five million bucks.

Dr. WYNGAARDEN. That is the first-year cost, yes.

Senator WEICKER. Well, I would imagine that you could probably apply $5 million to any one of those, never mind five of them. And that probably would still be insufficient funding, depending, I suppose, on what you deem to be the urgency of these various problems.

Dr. WYNGAARDEN. I should point out these are proposals for clinical trials, not for all the research that undergirds the clinical trial itself. If

we take the acquired immune deficiency syndrome as one example, we are this year spending close to $10 million in that area alone. And that is on top of about $200 million in the basic science related to the general problems of that syndrome—immune deficiency, Kaposi's sarcoma, T-cell function, and so on. Thus, the trials include testing at the last stage of introduction of an idea into the clinical arena. Clinical trials tend to become more expensive with time.

In 1983, for example, we will initiate 18 clinical trials at a cost of $15 million. The continuation costs will rise to $30 million for those same trials in 1984. Thus the $5 million in the 1984 budget is on top of another $30 million in trials initiated in 1983. And that is on top of some that have been ongoing for other years. So we have a sizable amount of money in the clinical trial category.

ACQUIRED IMMUNE DEFICIENCY SYNDROME

Senator WEICKER. Well, what are you indicating to me, then? Let's take the immune deficiency syndrome. At what stage are we in terms of having the answer to that problem?

Dr. WYNGAARDEN. We have a great deal of work to do to understand that basic condition. Research is going on at multiple levels. What we have proposed in the 1984 clinical trial is a specific project evaluating the effects of theta and gamma interferon in certain stages of that disease as treatment modalities. That is a very small fraction of the total effort.

Senator WEICKER. I am on a pretty tight schedule here with so many to hear from. I have got other questions which I would appreciate that you would respond to for the record.

Dr. WYNGAARDEN. We would be happy to do that.

BUDGET PROCESS

Senator WEICKER. But let me say this—and I think we have really had a fairly good exchange on the main areas that relate anyway to your testimony, and your overall leadership of this agency—that my staff will be in close contact with you in the weeks ahead.

What we have before us was only received on Friday evening.

Now, how many people do you have in your agency?

Dr. WYNGAARDEN. We have over 12,000 people at the Bethesda campus.

Senator WEICKER. How many do you have in your financial section?

Mr. ITTEILAG. About 50 for the whole Department.

Senator WEICKER. About 50 for the whole Department against 12,000; right.

Who else is involved in this budgetary process besides 12,000 and 50? Do you know how many I have got? You see a few of them back here. I have got about 9. And for me to go ahead and receive a complex budget such as this on Friday night for a hearing on Monday, to me shows a disregard for the congressional process or an assumption that we are all going to sit here and swallow it.

And I will tell you, I have too much respect for the scientific community to discharge my functions in such a manner. So that is why I say that there will be additional communication, not only in response to questions for the record, but in trying to pin down various aspects of this budget in a way that the committee will deem satisfactory in terms of its congressional oversight.

I would also say this that as much as I respect you, Dr. Wyngaarden and your past leadership, I have some grave reservations about what it is the administration is doing in this area. And you might not be asking for more funds, but you are going to be in that very rather unique position of possibly getting more funds, as this constitutional process involves both the legislative and the executive branch.

I have never known how science accomplishes anything on the cheap. And I am not willing to balance the budget today or give the appearance of doing something to hold down Federal spending, which I know is going to exact a terrible cost in the out years when the players on this stage are long gone—long gone.

You know that, and I know that. And the politicians can screw around all they want in terms of getting votes, and sometimes it doesn't bother me, but when we are talking about suffering and death, it certainly does.

And I think this is an underfunded budget and one that is being forced probably into that channel by an excessive concentration on other priorities which coincidentally try to achieve the maximum in death and suffering.

Thank you.

PREPARED STATEMENT AND SUBMITTED QUESTIONS

Senator WEICKER. Thank you, we will place your prepared statement in the record at this point along with the additional questions.

[The information follows:]

Statement of Dr. James B. Wyngaarden

I appreciate this opportunity to speak in behalf of the President's proposed fiscal year 1984 budget for the National Institutes of Health, to report on the state of the national biomedical research enterprise, and to note some of the benefits flowing from the public investment in health sciences research.

This is my first appearance before this Subcommittee. I became Director of NIH last spring when the process was already under way. I look forward to working with you, Mr. Chairman and Members of the Subcommittee, as we chart the course for continued progress in biomedical research.

I want to emphasize that, when speaking of NIH and its programs, we are referring to a nationwide collaborative research network created by a multibillion-dollar public investment during the past 30 years. The broad base of the network is indicated by a few statistics: the Federal Government supports an estimated 90 percent of basic biomedical research in this country; more than 60 percent of funding for health science research and development at American universities and medical schools is channeled through NIH; and four of every five dollars of the NIH budget go, through extramural awards, to support thousands of investigators and hundreds of institutions engaged in biomedical research.

The Federal investment, in other words, supports a national health sciences research venture with many participants--a research community made up of investigators in publicly and privately supported colleges, universities and medical schools, the laboratories of industry, and voluntary organizations and foundations. The primary objective of that diverse partnership with Government is to generate fundamental biomedical knowledge and, ultimately, to apply it to the prevention, treatment, and cure of disease and disability. The collaboration has brought us through what you have heard described as a "biological revolution" into the molecular age of the health sciences. Because we are able now to study the smallest details of the processes of life, and the details of those details, we are on the threshold of greater health advances than ever before.

As a scientist, I know predictions in this field are risky. But the research and development capacity we have generated in the past decades justifies optimism about prospects for the understanding and control of major diseases. That confidence rests on basic discoveries that have already made possible recombinant DNA and hybridoma technologies with their potential for diagnosis and intervention in the mechanisms of life and disease. We are moving steadily toward the understanding of major maladies such as cancer, cardiovascular disease, arthritis, diabetes, and disorders of the brain and nervous system.

We have a long way to go, of course; many of the essential pieces of fundamental information have yet to be discovered. But today's knowledge and technology enable us to pursue a rational course toward greater understanding and new methods to prevent and treat disease.

We are enjoying the benefit of what Arthur Kornberg, Nobel laur-

eate and member of the NIH Director's Advisory Committee, has termed a "profound development in medical science." Dr. Kornberg described that development as a "confluence of the many discrete and previously unrelated medical science subjects into a single, unified discipline. Anatomy, physiology, biochemistry, microbiology, immunology, and genetics have now merged and are expressed in a common language of chemistry," he said, in stressing the importance of fundamental research.[1] That common language of modern science is "spoken" throughout the research supported by NIH as investigators focus on the mechanisms of normal human development as well as on disease.

In summary, we have a thriving national biomedical research network ready to capitalize on the fundamental knowledge we possess and to pursue still-undiscovered pieces of essential information. Continued progress requires that we maintain the momentum of discovery even though the national economy demands restraint on Federal spending. Before going further, I would like to mention a few of the benefits we are reaping today from the public investment in basic and clinical biomedical research.

First, I would like to cite a few examples of the health benefits possible today:

- o A highly effective vaccine to prevent hepatitis B, a serious viral infection of the liver, is now available. Acute hepatitis B affects some 800,000 Americans annually and mass immunization with this vaccine could sharply reduce that number. The vaccine, developed with significant NIH research support, may also help reduce morbidity and mortality from chronic active hepatitis and cirrhosis of the liver. It may also help prevent liver cancers that have been linked epidemiologically to hepatitis B infection.

- o An estimated 70,000 Americans each year can now be spared severe visual impairment from senile macular degeneration (SMD), an eye disease that is a leading cause of blindness. Results of an NIH-supported clinical trial show that treatment with a laser can dramatically reduce the risk of visual loss from the neurovascular type of this disorder characterized by the formation of abnormal new blood vessels in the eye.

- o A highly promising drug treatment to dissolve cholesterol gallstones, developed and tested with NIH support, is awaiting approval by the Food and Drug Administration. About 500,000 gallbladder operations are performed annually in the United States at a cost of $1 billion. Drug treatment could provide an alternative to surgery in some cases.

The long-range outlook for understanding major chronic diseases and disorders in the coming years is also very promising. You will hear reports on progress and prospects in those areas in detail from subsequent witnesses in these hearings.

There is also the economic payoff. Direct dollar-to-benefit accounting in scientific research is difficult, but let me cite just one study of such returns. An economic analysis of the period

1. Kornberg, A., "Biology and Technology," Address, San Francisco, California, April 13, 1982, p. 6.

1900 to 1975 estimated savings from reduced morbidity and mortality attributable to health science research at between $300 and $480 billion. Even the lower of these figures indicates a return of at least $10 for every dollar invested in health research.[2] Economic considerations, of course, don't tell the whole story--the transfer of knowledge to medical practice means lives saved and suffering relieved.

These examples represent the many kinds of health and economic benefits possible today, thanks to discoveries in basic and clinical research, their testing by clinical trials and other studies and, finally, transfer to medical practice. My point, Mr. Chairman, is that while we cannot predict the timing or precise direction of progress in fundamental research, significant health benefits flow regularly from the research enterprise as a whole. Pursuit of basic knowledge by many investigators following their own curiosities, insights and wisdom is what powers American research. And, Federal support is the essential element in the success we enjoy, as many Administrations and Congresses have recognized and affirmed through generous support over the years.

Since 1973, NIH appropriations in terms of constant dollars have remained relatively level. This steady-state funding situation intensifies competition for Federal research support among the areas for which NIH is responsible--extramural research project support, intramural programs, training of investigators, clinical trials, upgrading and renovation of facilities, and development of highly sophisticated instrumentation essential to modern biomedical research. And, since our fundamental mission is the improvement of health and well-being, we must also emphasize prevention of disease and disability, by making a special effort to see that scientific discoveries are transferred to medical practice as quickly as appropriate.

Within the context of a relatively constant budget in recent years, we have sought to emphasize stability in the research project base. As I have said repeatedly, pursuit of fundamental knowledge is the foundation of progress in the health sciences and investigator-initiated research holds the greatest promise of significant discovery. Accordingly, NIH has increased the share of total appropriation devoted to research project grants from 38.5 percent in 1977 to 51.3 percent in the 1983 budget.

As a result, despite inflation, we have been able to keep the level of support for new and competing research project grants fairly even. In 1981, we supported 5,109 grants and, 1982, 5,027 grants. The 1983 budget will enable us to support 4,914 new and competing grants out of a total research project grant portfolio of 16,357 projects.

To maintain a relatively stable level of research project grants will require continued shifts in support from other mechanisms, as well as aggressive efforts to hold down the average cost of grants. In 1982 and 1983, we were able to reduce the costs by approximately 4 percent in noncompeting grants. In the case of new and competing

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2. Mushkin, S.J., 1979, "Biomedical Research: Costs and Benefits," Cambridge, Massachusetts, Ballinger, p. 412.

grants, we have negotiated about 7 percent below study-section-recommended levels.

The President's proposed fiscal year 1984 budget for NIH of $4.077 billion represents a $73 million increase over the current year. The fiscal year 1984 budget will support 5,000 new and competing project grants. In order to fund the 5,000 grants, we will again conduct downward negotiations in non-competing grant average costs and make reductions from study-section-recommended costs for new and competing grants. We will fund most other mechanisms at approximately the 1983 level. Two exceptions are the research centers program and biomedical research support grants where the proposed funding levels are below 1983.

We also intend to reduce indirect cost reimbursement to grantee institutions as a cost reduction measure. There has been a sizeable increase in indirect costs over the past decade. The level, as a percentage of total research grant costs, increased from 20.6 percent in 1972 to about 30 percent in 1982. While we recognize that indirect costs are legitimate costs of research, NIH believes that its expenditures for indirect costs should be adjusted downward as has been done with direct costs. The 1984 request assumes total indirect cost reductions of about $72 million from levels that would result without a containment policy.

As directed by the Appropriations Committee, we have carefully reviewed indirect costs and consulted with universities and other research organizations most directly affected. We are completing a report that contains conclusions and recommendations for discussion.

Among our other priorities, we continue to emphasize research training. It is essential that we support the training of new investigators to assure continuity of high-quality research in the future. The fiscal year 1984 budget would support about 9,076 research trainees, compared to approximately 9,969 in the current year.

I should also mention that the budget includes $5 million for 5 major new high-priority clinical trials. They include additional research into the acquired immune deficiency syndrome (AIDS) and the Kaposi's sarcoma problem, evaluation of biological response modifiers, studies of monoclonal antibodies as carriers of toxins, development of standards for initiation of kidney dialysis, and development of a vaccine for herpes simplex virus.

That concludes my summary statement, Mr. Chairman. I will be pleased to answer any question you or Subcommittee members may have.

Biography of Dr. James B. Wyngaarden

JAMES BARNES WYNGAARDEN, M.D.

Present Position: Director, National Institutes of Health
Building 1, Room 124
9000 Rockville Pike
Bethesda, Maryland 20205

Place and Date of Birth: East Grand Rapids, Michigan, October 19, 1924

Education and Degrees:

1942-1943	Calvin College, Grand Rapids, Michigan
1943-1944	Western Michigan University, Kalamazoo (Navy V-7 Program)
1948	University of Michigan Medical School, M.D. (cum laude)
1980	University of Michigan, D.Sc. (honorary)

Clinical and Research Training and Academic Appointments:

1946-1948	Research Assistant in Pharmacology, University of Michigan Medical School
1948-1949	Intern in Medicine, Massachusetts General Hospital, Boston
1949-1950	Assistant Resident in Medicine, Massachusetts General Hospital
1950-1951	Assistant to Dr. Walter Bauer (Rheumatology Practice), Massachusetts General Hospital
1951-1952	Resident in Medicine, Massachusetts General Hospital
1952-1953	Visiting Investigator, Public Health Research Institute of the City of New York, Inc.
1953-1954	Research Associate, Laboratory of Chemical Pharmacology, National Heart Institute, National Institutes of Health
1954-1956	Clinical Associate, National Institute of Arthritis and Metabolic Diseases, National Institutes of Health
1954-1956	Clinical Instructor in Medicine, George Washington University, Washington, D.C.
1956-1959	Associate Professor of Medicine, Duke University Medical Center, Durham, North Carolina
1959-1961	Associate Professor of Medicine and Biochemistry, Duke University Medical Center
1961-1965	Professor of Medicine and Associate Professor of Biochemistry, Duke University Medical Center
1963-1964	Visiting Scientist, Institut de Biologie-Physiochemique, Paris
1965-1967	Frank Wistar Thomas Professor and Chairman, Department of Medicine, and Professor of Biochemistry, University of Pennsylvania School of Medicine, Philadelphia
1965-1967	Physician-in-Chief, Medical Service, Hospital of the University of Pennsylvania
1967-1982	Frederic M. Hanes Professor and Chairman, Department of Medicine, Duke University School of Medicine
1981-1982	Physician-in-Chief, Medical Service, Duke University Hospital
1981-1982	Chief of Staff, Duke University Hospital
1982-	Director, National Institutes of Health

Positions Held on Committees, Boards, Societies, and Journals:

U.S. Atomic Energy Commission
Advisory Committee on Biology and Medicine, 1966-1968

Advisory Council, Life Insurance Medical Research Fund, 1967-1969

Medical Advisory Board, Howard Hughes Medical Institute, 1969-

Board of Scientific Counselors of the National Institute of Arthritis and Metabolic Diseases, 1971-1974

Board of Directors, The Royal Society of Medicine Foundation, 1971-1975

Board of Directors, Central Carolina Bank and Trust Company, 1972-1975

National Board of the Robert Wood Johnson Foundation Clinical Scholar Program, 1973-1978

National Academy of Sciences-National Research Council
NRC Committee for Study of National Needs for Biomedical and Behavioral Research Personnel, 1975-1982, and Vice-Chairman, 1977-1981
Executive Committee, Assembly of Life Sciences of National Research Council
National Research Council Division of Medical Sciences (representing the American Society of Biological Chemists), 1971-1974

Advisory Board, Science Year, 1977-1981

Chairman, Local Chapter, NIH Alumni Association, 1977-

Editorial Boards: Annals of Internal Medicine, Arthritis and Rheumatism, Journal of Biological Chemistry, Journal of Clinical Investigation, Medicine, Physiology for Physicians, and Proceedings of the National Academy of Sciences

Editor:

Cecil Textbook of Medicine (16th edition), J. B. Wyngaarden and L. H. Smith (Eds.), W. B. Saunders. Co., Philadelphia. 1982.

The Metabolic Basis of Inherited Disease (5th edition), J. B. Stanbury, J. B. Wyngaarden, D. S. Fredrickson, J. L. Goldstein, and M. S. Brown (Eds.), McGraw-Hill Book Co., New York, 1982.

Review of General Internal Medicine (2nd edition), L. H. Smith and J. B. Wyngaarden (Eds.), W. B. Saunders Co., Philadelphia, 1982.

International Textbook of Medicine, A. H. Samiy, L. H. Smith, and J. B. Wyngaarden (General Eds.), W. B. Saunders Co., Philadelphia, 1981-1982.

Honors, Special Appointments, and Other Scientific Recognition:

University Scholar in Professional Schools (Medical), University of Michigan, 1946

First Honors, Class of 1948, University of Michigan Medical School

First Annual Borden Undergraduate Research Award in Medicine, University of Michigan, 1948

Dalton Scholar in Medicine Fellowship, Thyroid Laboratory, Massachusetts General Hospital, 1950

Consultant to the Durham Veterans Administration Hospital, 1956-1965 and 1967-1982

Cardiovascular Study Section, NIH, 1958-1960

General Medicine Study Section, NIH, 1960-1963

Consultant to the Philadelphia Veterans Administration Hospital, 1965-1967

Consultant to the Office of Science and Technology, Executive Office of the President, 1966-1972

Chairman, Medical Scientist Training Committee, NIH, 1967-1969

Sesquicentennial Award, University of Michigan, 1967

Distinguished Alumnus Award, Calvin College, 1970

Appointed to the President's Science Advisory Committee, 1972

Consultant to the Food and Drug Administration, 1972-1973

Editorial Consultant to MEDCOM, Inc., 1972-

Modern Medicine Distinguished Achievement Award, 1974

Election to the National Academy of Sciences, 1974

North Carolina Governor's Award in Science, 1974

Election to the American Academy of Arts and Sciences, 1976

Appointed to the President's Committee for the National Medal of Science, 1977-80

Founder's Medal, Southern Society for Clinical Investigation, 1978

The John Phillips Memorial Award, American College of Physicians, 1980

Honorary Membership in the Sociedad Medica de Santiago de Chile, 1981

Membership in Professional Societies

Alpha Omega Alpha, University of Michigan

American Academy of Arts and Sciences (Fellow)

American Association for the Advancement of Science

American Board of Internal Medicine

American Clinical and Climatological Association

American College of Physicians

American Federation for Clinical Research

American Rheumatism Association

American Society for Clinical Investigation

American Society of Biological Chemists

Association of American Physicians; Councillor, 1973-78, and President, 1977-78

Endocrine Society

Institute of Medicine

Interurban Club

Italian Society of Rheumatology (Honorary), 1961

Laurentian Hormone Conference, 1954-1958

National Academy of Sciences

Southern Society for Clinical Investigation; President, 1974

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Questions Submitted by the Subcommittee

NEW BUDGET EFFECTS

Question: The revised NIH budget provides an additional $140.9 million to increase the number of new research grants from the 3,676 requested in January to the 5,000 grants that are considered the stability level for the Institutes. What will these additional 1,324 grants produce in the way of additional research?

Answer: The additional 1,324 grants will enable NIH to stabilize support for research project grants -- the principal mechanism for generating new biomedical knowledge. Additional research will be supported in all the Institutes; for example, in such priority program areas as radiation, epidemiology, physiology of tissue, inherited disorders, the role of the immune system, senile dementias, rehabilitation of patients with chronic disease, behavior, prevention, diagnosis, metabolism, hematology, transplantation, biological response, and cancer chemoprevention.

Question: The revised budget makes the biggest cuts in research centers, biomedical research support grants, research and development contracts and in continuation grants. These cuts total $111 million out of the $140.9 million shifted by the revised budget. What will be the impact on research from these specific reductions?

Answer: In general, the impact on research from reducing these mechanisms will be slowed progress in the generation of new research, postponement of clinical trials, less dissemination of new biomedical knowledge to the community, and delayed development and supply of resources (e.g., biologics, drugs, animals) used for research. More specifically:

Specialized/comprehensive research centers provide a single administrative and programmatic structure for clinical and laboratory research, education, training, and community outreach. The reduction in 1984 includes a 16-percent decrease in the number of centers from the 1983 level and a drop of 15 percent in dollars from the 1983 funding level. The centers being eliminated constitute a majority of those coming up for renewal. Centers for which continuation funding has been committed will not be eliminated.

BRS grant reductions will affect such activities as pilot research, support of new investigators, and interim support, which maintains research during temporary interruption of research grant support. The portion of the BRS program related to instrumentation will not be reduced since this program is crucial to maintaining research capability in the Nation's universities.

The primary impact of the reductions in R&D contracts will be to delay about 13 new major clinical trials. The revised funding level will maintain ongoing commitments as well as provide for five new clinical trials.

The draft budget submitted in January assumed reductions of approximately 5 percent in noncompeting research project grants from the full cost of the recommended levels. The current plan will

implement reductions of 6 percent, which will require further belt-tightening by the grantees. It should be noted, however, that the average cost of a noncompeting award will increase by approximately 4 percent over the average FY 1983 award rate for noncompeting grants. Despite these further reductions in continuation funding from recommended levels, the scope of the projects should not be significantly affected.

INDIRECT COSTS

Question: At the request of Congress, you were asked to consult with the biomedical research community about concerns over indirect costs of research. Have such consultations taken place? (We understand that the only meeting was last February 17.)

Answer: A formal meeting was held on February 17, 1983, between PHS officials and representatives of the biomedical research community at which the indirect cost problem was discussed and views exchanged. This dialogue will be continued with the purpose of developing practical short- and long-term solutions to a mutual problem, including exploration of the feasibility and desirability of redefining reimbursable indirect costs. The indirect cost report that we submitted to the Committee includes papers expressing the views of some of the representatives of the awardee community.

Additional consultation has taken place informally in the form of letters and phone calls from members of the research community informing us of their views and recommendations.

Question: Did the extramural research community agree that your proposed $72 million cut in reimbursement of indirect costs was equitable?

Answer: While I cannot answer for the research community in general, the comments we have received to date indicate strong opposition by university administrators to the $72 million reduction on the basis that further discussion and study of the problem should be undertaken. Comments from a number of individual research investigators generally are supportive of some reduction of indirect costs.

Question: The Subcommittee is aware of the significant problems of aging facilities and obsolete equipment in universities doing research. What will be the effect of the cut you propose on the universities' ability to host the Nation's biomedical research?

Answer: Equipment is funded as a direct cost, so proposals to reduce indirect costs should have little, if any, impact on equipment acquisitions under grant support.

Question: How will the universities be able to absorb the $72 million cut -- or do you expect them to raise tuition further to pay for the support of Federally sponsored research?

Answer: The indirect cost containment strategy we recommend -- tailoring indirect levels in FY 1984 to an institution's historical experience -- will require only minimal reductions in those institutions who have restrained indirect cost growth in recent years. The

major impact of the proposal will be felt by those grantees whose indirect costs have been growing most rapidly in relation to total costs. Those institutions will probably have to take a close look at some of their overhead functions to find ways to cut the departmental and general administration components of indirect costs. In some cases, it may be necessary to raise tuition.

Question: Your report to Congress on indirect costs, received just last night, appears to recommend putting a 25% floor under these costs. Would you explain what you have in mind -- and indicate whether you have discussed this and other ideas with university and other research officials?

Answer: We recommend the 25-percent floor in conjunction with the proposal to tailor each institution's indirect cost level to its own historial experience. This option will give an institution a level equal to its average percentage of total costs over the last decade. The 25-percent floor will apply to those institutions whose 10-year average would drop them below 25 percent, thus putting an outer limit on the severity of the reduction. Institutions whose current rate is already below 25 percent will not be affected by the proposal. In cases where the reduction will be severe enough to cause an undue operational burden, a formula will be used to phase in the reduction over a 2- or 3-year period.

Consistent with the Committee's intent, the DHHS has begun the process of consulting with representatives of research institutions for their views and concerns about each of the policy options described above. A PHS meeting with university officials and representatives of certain research societies was held on February 17, 1983, at which the indirect cost problem was discussed and views exchanged. This dialogue will be continued with the purpose of developing practical short- and long-term solutions to a mutual problem, including exploration of the feasibility and desirability of redefining reimbursable indirect costs.

PROTECTING FUNDS

Question: Dr. Wyngaarden, the Federal investment in NIH has been growing substantially. Back in 1975 Federal funding for your agency was at about $2.1 billion -- and in fiscal 1983 Congress gave you $4 billion for the first time. At a time when other programs are being held level or cut, yours goes up -- an enviable position.

As the new director, what steps are you taking, or will you take, to see to it that this money is well and carefully managed, and that we don't start hearing stories about waste or misuse of funds?

Answer: I believe the best step I can take in the foreseeable future to promote proper use of the funds appropriated to the NIH is to continue the practices of the recent past. The reputation of the NIH for prudent stewardship of funds ranks with its reputation as an invaluable contributor to the quality of our national life. I intend to see that both reputations continue to be deserved.

With specific regard to preventing waste and abuse of funds, I believe that the current system of prospective and retrospective reviews is excellent. Each Institute periodically must justify its

budget requests to me and often to higher levels of the Executive Branch; these justifications are assessed with respect to not only the merit of what is proposed but also the accomplishments to date. Similarly, each grant application and contract proposal must pass through a rigorous series of evaluations by peer reviews and staff; and the progress reports of awardees are reviewed at least annually by staff in terms of both scientific accomplishments and expenditure practices. Finally, awardee institutions are subject to independent audit by the cognizant Executive Department and the General Accounting Office.

Question: What, if any, administrative or reorganizational initiatives do you plan to take at NIH?

Answer: Aside from the intiatives related to misconduct in science, I have no plans at present for administrative or reorganizational initiatives associated with waste or misuse of funds. As indicated above, I believe the current practices are effective and deserve to be continued. The principal issues affecting the NIH organization are those related to whether new Institutes should be created or other PHS components should be transferred to the NIH. The NIH does not plan to make any significant organizational changes for such program or mission purpose until the Institute of Medicine completes a recently initiated study of our current organization and offers criteria to guide future organizational change.

FRAUD IN RESEARCH

Question: Over the past year, a number of cases of outright scientific fraud and low-quality research have been brought to light in leading medical schools which were receiving funding from NIH and other Federal entities.

Can you tell us what initiatives have been taken to monitor more closely the progress of extramural research and to prevent faked data from being generated?

Answer: The NIH and other research components of the Public Health Service (PHS) believe that fraud in science is best prevented by repeatedly promoting strict adherence to the highest standards of scientific practice and by dealing forcefully with the few serious cases of misconduct that almost inevitably occur each year. The vast majority of scientists are committed unequivocally to seeking new knowledge in ways that are as nearly honest and bias-free as is humanly possible. They need little, if any, reminder of the canons of behavior upon which their lives' work rest.

Having PHS staff monitor activities under grants and contracts more closely than they already do is likely to retard research progress to an extent out of all proportion to whatever small gain might be achieved in detecting or preventing aberrant behavior. And, having awardee institutions place their scientist employees under new forms of surveillance or subject them to significant new restraints is distinctly unappealing. Detection or prevention of fraud on the part of a figurative handful of scientists would be bought at a terrible price -- the abrogation of the tradition of largely unencumbered inquiry that has made science in general, and institutions of higher education in particular, indispensable to our civilization.

During the past year, the NIH, as the lead agency for the PHS in dealing with misconduct in science, has been directing an effort to develop a refined and extended set of policies and procedures relevant to instances of real or apparent wrongdoing. These policies and procedures to a considerable extent are a codification of the current administrative practices of the PHS agencies -- practices which they have evolved in handling the cases to which the question refers. The policies and procedures are intended to be comprehensive and therefore include sections on the responsibilities of awardees and their relationships with the sponsors. The PHS plans to distribute this material broadly in the near future. The information should help awardees, their scientist employees, and PHS staff maintain the levels of quality, objectivity, and integrity the public rightfully expects of those accorded its patronage.

It is noteworthy that within the past year both the Association of American Medical Colleges (AAMC) and the Association of American Universities (AAU) have published general guidance for their member institutions with respect to misconduct in science. The PHS strongly endorses the thrust of both statements, finding them highly compatible with the emerging PHS policies and procedures mentioned above. There is every reason to believe that there will be strong and sustained cooperation between PHS research agencies and their awardees in dealing with instances of real or apparent misconduct.

Notwithstanding the widespread commitment to promoting proper scientific practice, instances of serious misconduct almost surely cannot be prevented entirely; in the last analysis, fraud in science is rooted in human failings. The PHS, when faced with real or apparent wrongdoing, therefore intends to continue acting promptly, forcefully, unequivocally, and visibly to deal with the individual matters. In particular, the PHS will continue to impose significant sanctions such as termination of awards, disallowance of awardee expenditures, and debarment of individual scientists whenever misconduct is judged to have been serious. Although relatively infrequent -- befitting the very low incidence of significant misconduct -- such demonstrations of seriousness of purpose on the part of the PHS should serve to deter wrongdoing by at least some of those few who might otherwise lose sight of the principles of objectivity and integrity which characterize science.

Question: How serious is this problem, and how can it best be solved?

Answer: When looked at strictly in terms of numbers, the problem of falsification and misrepresentation in biomedical research is almost trivially small. There have been on the order of a dozen or fewer allegations per year in recent years out of an array of more than 20,000 active awards. Not more than half of these have been substantiated. There is little reason to be concerned that the fabric of science is soiled by a large or spreading stain.

When viewed qualitatively, however, the problem of misconduct in biomedical research is extremely serious. Almost every case receives considerable publicity -- often prematurely and frequently inaccurately. Each case therefore is a threat to continued public confidence in science and those who administer funds to foster the search

for new knowledge. Each case also has the potential for ruining the careers of innocents and wrong alike. It is for these reasons that the PHS is according the matter high priority and is acting as described above.

Question: To what extent are the standard mechanisms by which scientists check their colleagues' work sufficient to detect, or even deter fraud?

Answer: The PHS believes that the standard processes of science -- particularly peer review of proposed publications and independent repetition of crucial experiments -- are far and away the best means to detect and deter fraud. Recent assertions in newspapers and books to the contrary, virtually every significant incident of misconduct has been uncovered at least in part by the operation of these processes. That is not to say that they are perfect or that less traditional means such as "whistleblower" reports are of no value. Rather, close examination of case histories makes clear that other scientists ultimately contribute invaluably -- in fact, and uniquely -- to detecting misconduct by their peers. It is most unlikely that the Federal Government could increase the frequency of detection or augment deterence without restraining scientific inquiry to an unacceptable degree.

BIOBEHAVIORAL RESEARCH

Question: As you know the reputable Institute of Medicine issued a report last year indicating that life style may be a strong influential factor in the development of disease. Smoking, use of alcohol and illicit drugs and stress come immediately to mind.

How will the IOM report influence the course of research at NIH to take account of the role of behavior in disease?

Answer: The report of the Institute of Medicine (IOM) is an articulate and well-documented statement of a conviction that has been growing in recent years -- that life-style is an important contributory factor in the development of many of the major diseases that affect Americans today. Life-style, unlike age, sex, and genetic constitution, is subject to the control of the individual, so that the delineation of those aspects which are detrimental to health offers a real prospect for successful prevention of illness.

The NIH has been in the forefront of these developments, and intends to remain so. We sponsored the IOM study in part, and made major contributions to its successful completion. Much of the original scientific research on which the conclusions of the IOM are based was performed or sponsored by NIH. In chapter 7, on cardiovascular disease, the Nation's number one killer, there are citations of 48 original scientific studies since 1970. Thirty-two of these mention support by NIH, or were actually carried out here. Only six attribute sponsorship to an American source other than NIH; ten either do not include the information, or emanate from other countries.

With the upsurge of interest in behavioral medicine, the number of related research grant applications submitted has steadily increased. The volume was such that, by 1980, it justified the estab-

lishment of a new technical review group, the Behavioral Medicine Study Section, to assure expert peer review in this field. Our two largest Institutes, the National Heart, Lung, and Blood Institute and the National Cancer Institute, along with the National Institute on Aging, now have specific organizational units at the Branch level or higher that specialize in programs on behavior and health.

In summary, let me state that NIH is already very active in promoting research on the relation of life-style and behavior to health and disease. The IOM report is an excellent review of the current state of knowledge, and offers a thoughtful research agenda for the future. We expect to continue to exploit these opportunities for finding new ways to preserve health and prevent disease and disability.

Question: What should NIH be doing to get people thinking more about healthful behavior?

Answer: The NIH maintains a wide variety of public information programs, including regular news feature services, close collaboration with reporters and science writers from the major media, and responses to nearly half a million public inquiries each year. All these mechanisms are used to disseminate information about healthful behavior as reliable facts emerge from our research efforts.

Specific information programs have included NHLBI's health promotion activities in the area of smoking cessation, high blood pressure control, and exercise for cardiovascular benefit; NIA's newly developed "Age Page," a publication designed for the elderly population; NIDR's efforts at caries prevention through "Snack Facts"; NCI's large scale education/information programs on smoking prevention and cessation; and the Nutrition Coordinating Committee's "Eat Well, Be Well" series.

PAY TRANSFER

Question: Your budget requests a transfer of $2,299,000 from the Rural Development Loan Fund to cover fiscal 1983 pay costs of the Fogarty International Center, the National Library of Medicine, and the Office of the NIH Director. The Rural Development Loan Fund was set up to help fund development in rural areas. Because the Department dragged its feet on getting these funds out, our Committee directed that it expend $10 million from the program in fiscal 1982 and fiscal 1983. Why are you trying to divert money for rural economic development in order to pay the salaries of Federal staff in an entirely different program?

Answer: Since our budget was submitted in April, the amount proposed for transfer has been revised downward based on our latest review of pay costs. $1,424,000 is now proposed for transfer rather than $2,299,000. This includes funds to cover pay cost increased in the National Library of Medicine ($395,000) and the Office of the Director ($1,065,000). Additional transfers of $875,000 included in the President's budget are no longer required for the National Library of Medicine ($712,000) and the John E. Fogarty International Center ($163,000). The amounts proposed for transfer from the Rural Development Loan Fund (RDLF) to cover pay and related costs have

been determined by the Department to be in excess of FY 1983 program needs. Consistent with Congressional intent as expressed in the Second Continuing Resolution (P.L. 97-377), the Department plans to use $10 million in fund balances for loan guarantees in FY 1983. At the same time, the Administration's FY 1984 budget proposes to terminate the RDLF as other agencies (Small Business Administration, Farmer's Home Administration [USDA]) already run an array of programs designed to address similar problems and constituencies. Therefore, because monies remaining in the fund will not be needed beyond FY 1983, the Department has determined that it is reasonable and appropriate that they be transferred to offset pay raise and other administrative costs in program areas that cannot afford to pay these costs from existing resources.

Question: Why don't you send up a supplemental request if you really need the money for pay? There always seems to be unobligated funds available under the old swine flu appropriation -- have you looked at that possibility?

Answer: With the excess of funds in the Rural Development Loan Fund, the Department considered it more appropriate to seek authority to use these funds as opposed to seeking new funds.

Question: Wouldn't your proposed transfer require legislation in order to carry it out? It isn't a simple reprogramming.

Answer: Yes. These transfers require appropriation action to permit the use of these monies for pay cost increases. A reprogramming action is not sufficient since the funds will need to be transferred from the Rural Development Loan Fund account to the three NIH accounts.

OTHER CUTS

Question: Your revised budget proposes to cut administrative supplemental awards by 282 for a decrease of $7.8 million. What do you use these awards for and what will be the impact of such a cut?

Answer: Administrative supplemental awards serve three key functions:

- Termination funding -- When a research project grant has run its course and a competing renewal grant has been unsuccessfully applied for, it is sometimes necessary to provide additional funds to finish up several key elements of the grant to ensure an adequate report; prevent an abrupt, traumatic termination of activity; or permit alternative sources of funding to be pursued for a non-renewed, but nonetheless worthwhile, project.

- Interim funding -- Occasionally, a research project grant near the end of its grant period will be considered reasonably certain to be renewed because of its good score but will be delayed in the review process. As a result, a gap can be expected to occur between the end of one grant and the start of the next. In such circumstances, interim funding may be provided to prevent major disruption in the overall effort.

- o Unanticipated costs -- Sometimes, additional, unanticipated costs arise during the grant period; e.g., system-wide pay raises, higher-than-planned-for costs for equipment, or the failure of an estimated unexpended balance to materialize from a previous grant. In such instances, administrative supplemental awards may be granted.

It should be noted that none of the above functions entails an expanded scope of work. When that happens, applications for competing suplemental awards must be submitted.

Cutting administrative supplemental awards by close to half is being proposed as part of the effort to make sufficient funds available to achieve NIH's key priority of stabilizing the number of new and competing awards at about 5,000 per year. This reduction, in light of the functions described above, will not be without at least some hardship and loss of potential research results. These funds are already closely monitored so that only the most deserving awards are made. There may be some instances where individual Institutes will, as a result of this cut, have to use other funds to protect the much larger research investment already made for a particular project.

Question: Also, please explain the impact on your research program of the following reductions:

-- $2 million for Research Cancer Development awards;
-- $1.8 million from Cooperative Clinical Research awards;
-- $2.0 million from Clinical Education awards;
-- $5.0 million from training, including the 5% stipend increase;
-- $3.4 million from intramural research; and
-- $0.6 million from direct operations.

Answer: The revised budget proposes a reduction of about $2.1 million or 52 awards from the January budget submission for research career development awards. This represents a total reduction of about 4.0 percent in numbers of awards and 3.6 percent in dollars. The reduction will be spread among most of the Institutes. It should, however, be noted that the revised request is still about $1.9 million higher than the level currently available in FY 1983 and provides for approximately the same number of awards.

The revised budget also calls for a reduction of $1.8 million for the cooperative clinical research program within NINCDS. This will eliminate four new clinical trials originally planned for FY 1984 on cochlear implants, multiple sclerosis, control of neurological complications of diabetes, and fluorides in prevention of otosclerosis. Compared to FY 1983, the revised request reflects a $2.6 million increase for the total cooperative clinical research program but a decrease of 10 awards.

A reduction of $2.0 million and 26 awards in NCI's clinical education program is proposed in the revised budget for FY 1984. This represents the same dollar level but five fewer awards than in FY 1983. Essentially, the FY 1984 revised budget postpones the planned expansion of the newly redesigned clinical education program.

In addition, the revised budget further decreases research training by 24 trainees and $5.0 million. Most of this reduction is due to the elimination of the proposed 5-percent stipend increase, which is consistent with the President's proposal to freeze Federal pay levels. The decrease should have minimal adverse impact on the NIH research program.

The revised budget will also reduce the NIH intramural program by about $3.4 million by postponing purchase of equipment and supplies for the ambulatory care research facility and by delaying expansion of research efforts in program areas such as modified techniques of molecular biology, genetic basis of diabetes, development and use of monoclonal antibodies against specific lymphocyte populations, clinical genetics, epidemiology, and health statistics.

Direct operations are also reduced by about $0.6 million in the revised budget; of this amount, $0.5 million would come from eliminating additional international research fellowships in the Fogarty International Center, and $0.1 million from postponing expansion of computer applications in the administrative data base.

OCCUPATIONAL SAFETY INSTITUTE

Question: There has been a good deal of talk about organizational changes at NIH. One of the most recent involves shifting the National Institute of Occupational Safety and Health (NIOSH) from the Centers for Disease Control to NIH. What is your view of this idea?

Answer: We believe the basic mission of NIOSH is not compatible with that of NIH; therefore, we would not support a transfer from CDC.

Question: How would it mesh -- or conflict -- with the work you presently do?

Answer: There are several aspects of NIOSH that would be unique in the context of NIH, and it is unlikely that these activities would mesh with the present mission of NIH. The following are examples:

NIOSH is mandated to respond to requests for health hazard evaluations. This service activity brings NIOSH into daily contact, sometimes confrontational in nature, with industry. To do this work, NIOSH is authorized to use warrants and subpoenas in execution of right-of-entry and right-of-access to data.

NIOSH is authorized to recommend health-based standards to the Occupational Safety and Health Administration and the Mine Safety and Health Administration. This requires integration of results of specific NIOSH research, other research, and prudent public health concerns into major policy pronouncements. These recommendations are usually controversial because they require changes in the workplace environment and often have financial implications if implemented.

CDC is the principal agency of the PHS concerned with the prevention of unnecessary illness and premature death. NIH, on the other hand, by stimulating and supporting basic investigator-initiated research, works to improve human health by acquiring new scientific knowledge.

Occupational safety and health research as performed by NIOSH focuses heavily on identifying and characterizing workplace conditions that cause disease or injury and on recommending technologies for prevention. This requires an emphasis on subjects not generally within the purview of NIH (safety, mining, and engineering) and outside the mission of NIH (e.g., regulation and service).

CDC and NIOSH serve a different "constituency" than NIH. NIH relates to academic institutions and other organizations involved in conducting basic medical research. CDC relates to those groups primarily concerned with applying state-of-the-art knowledge to prevention and control of illness and injury: international, national, state and local health agencies, voluntary agencies, associations, and others in the public health community applying prevention programs. The primary users of NIOSH are the occupational health and safety professionals in such settings.

Question: Organizationally where would it fit in?

Answer: As indicated earlier, we do not believe that NIOSH should be placed in NIH. We feel that it is premature at this time to speculate on any organizational placement within NIH. As you know, we have recently initiated through the Institute of Medicine (IOM) of the National Academy of Sciences a comprehensive evaluation of the organization of NIH. We have asked the IOM to: conduct a thorough, systematic review of NIH's organizational evolution and development and examine the present structure of NIH and its underlying rationale; examine NIH's present approach to those issues which cut across organizational lines and develop alternative approaches for consideration; and, in light of scientific developments and economic conditions, develop a rationale and criteria on which to base future changes.

TECHNOLOGY TRANSFER

Question: Last year the Office of Technology Assessment issued a report identifying weaknesses in the government's approach to transferring research results to those who can put them to practical use. OTA concluded that NIH "could devote more funds and attention to generating information on the potential benefits and risks of technologies -- and could actively utilize its existing, adequate mechanisms to support appropriate transfer of medical technologies." What action have you taken to address the weaknesses identified by OTA?

Answer: The consensus development process is a principal mechanism for technology assessment and transfer at the NIH. In reviewing a proposed topic for a consensus development conference, the Office for Medical Applications of Research (OMAR) and the cosponsoring Institute(s) examine carefully whether an adequate data base for a technology exists before proceeding with plans for a consensus conference. Under no condition will NIH evaluate a technology using the consensus process without a satisfactory knowledge base.

NIH shares OTA's concern that sufficient attention be paid to the "scientific evaluation of emerging technologies to determine their potential benefits, risks, costs, and conditions for appropri-

ate use." OMAR has placed increasing emphasis on the importance of selecting emerging technologies for evaluation through the consensus development mechanism. The upcoming consensus conference on liver transplantation serves as one example of NIH's commitment to this principle. It must be pointed out, however, that the mission of NIH is to support and conduct biomedical research; therefore, NIH does not possess the expertise required to evaluate the economic and social issues associated with medical technologies. For this reason, NIH has focused consensus conferences on issues related to the safety, efficacy, and indications for use of the technologies under evaluation.

Question: Your work in this field is done mainly through the Office for Medical Applications of Research. How well staffed and funded is this office to do the job expected of it?

Answer: The Office for Medical Applications of Research (OMAR) has five professional and four support staff members. For fiscal year 1983, $1.9 million has been allocated to OMAR for its technology assessment and transfer activities, evaluation studies, and general staff and operating costs. Additionally, each of the Institutes devotes staff and funds to the transfer of technology.

CLINICAL INVESTIGATORS

Question: The Committee understands that NIH data indicate that the number of physician researchers has not decreased significantly over the past 10 or 15 years, but that the number of Ph.D. researchers has increased rapidly, resulting in a sharp decrease in the percentage of physician investigators. Would you please provide us with information on the number of young M.D.'s entering the field of biomedical research each year, for the past few years?

Answer: The most recent data show that in FY 1980 there were 1,301 new principal investigators on all types of investigator-initiated research grants; 961 held the Ph.D. (73.9 percent) and 316 (24.3 percent) held the M.D. or the M.D./Ph.D. This number compares with 1971 when there were 817 new principal investigators, of whom 530 (64.9 percent) held the Ph.D. degree and 270 (33 percent) held the M.D. or the M.D./Ph.D.

These figures demonstrate an increase in the number of individuals with professional degrees serving as new principal investigators on grants but a decrease as a percentage of the whole over the decade beginning in 1971.

Question: In addition, since there are so many Ph.D. researchers available, would it be possible to develop programs to encourage and/or train them to do clinical research?

Answer: The least ambiguous definition of clinical research is research which involves a patient-doctor relationship. With the exception of some epidemiologists, clinical psychologists, and others working in behavioral science disciplines, the Ph.D. investigator is not qualified or authorized to assume such responsibility for meeting the health needs of others. Clinical investigation is necessary to the final translation of laboratory results to the prevention of

disease or the institution and supervision of therapy. Many Ph.D. investigators are an indispensible part of collaborative research efforts involving both laboratory science and clinical application. This is much encouraged by the NIH, but the participation of Ph.D.'s in clinical research must stop short of actual application to patients.

GRANT APPLICATIONS

Question: Do the increasingly larger number of grant applications to NIH represent increasing numbers of researchers, more multiple applications from individual laboratories, or reapplications from investigators whose proposals were not funded on the first submission?

Answer: The number of competing research project applications submitted to NIH increased from 8,596 in FY 1972 to 16,989 in FY 1982. The continued increase in the number of these applications is due to all three factors mentioned in the above question.

NIH data show that the numbers of different applicant investigators increased from 7,624 in FY 1972 to 13,422 in FY 1980. The number of applications from individual "laboratories" as measured by the applications per institution has also increased. In FY 1972, 360 domestic institutions of higher education submitted 7,143 competing research project applications for an average of 19.8 per institution; in FY 1982, 376 institutions submitted 13,867 applications for an average of 36.9 per institution or almost double the earlier figure.

Multiple applications from individuals have increased in two different ways. Data based on 3-year averages of applications per applicant investigator probably indicate the revision of applications, and increased from 1.41 applications per applicant in the FY 1971-73 period to 1.54 in the FY 1979-81 period. However, there has recently been a dramatic increase in revised applications. In the period May 1979 - January 1980, revisions constituted 15 percent of all the competing research project applications submitted to NIH. Only 3 years later (for the period May 1982 - January 1983), the percentage had increased to 22 percent. In the January 1983 review cycle alone, it had increased to 27 percent.

DEVELOPMENTAL DISORDERS

Question: Since research in the field of child health and human development is supported by more than one Institute as well as other government agencies, the Committee would like to know what efforts are underway or planned to ensure coordination and cooperation in the field of developmental disorders?

Answer: Research concerned with child health and human development is indeed supported by many of the Bureaus, Institutes, and Divisions of the NIH. I have asked the Director of the National Institute of Child Health and Human Development (NICHD) to develop an inventory of all NIH support in this area, and I understand that it will be completed during this fiscal year. A number of trans-NIH issues have been identified for coordination in this general area. These include alcohol and alcohol abuse, congenital defects, cystic

fibrosis, diabetes, mental retardation, drugs and drug abuse, environmental pollutants, genetics, long-term care, and maternal and child health.

The NICHD also maintains close liaison with other Federal agencies that support research in the fields of developmental disorders to strengthen the total research effort and minimize duplication. Prominent among these in the Public Health Service are the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS), the National Institute of Allergy and Infectious Diseases, the Alcohol, Drug Abuse, and Mental Health Administration, and the Health Resources and Services Administration. In the Department of Education, liaison is maintained with the National Institute of Handicapped Research and the Office of Special Education and Rehabilitative Services.

A recent example of cooperation to address the problems of developmental disorders is an effort currently underway by NICHD and NINCDS to develop a research agenda by examining the prenatal and perinatal factors involved in brain injury and subsequent problems of development.

EMERGENCY FUNDING

Question: If a certain percent of the funds presently allocated to the individual Institutes were instead made available to the Director, to take advantage of the new opportunities and needs that may develop suddenly during the course of a fiscal year (e.g., the AIDS epidemic), would it be a help or a hinderance to the NIH in the carrying out of its mission?

Answer: While it is important for the NIH to be able to respond quickly to new opportunities, I do not believe that it is necessary to establish a set-aside fund for this purpose. The NIH has demonstrated a remarkable capability to adjust quickly, using existing mechanisms to meet emerging requirements. In responding to research needs in AIDS, for example, the NIH immediately focused necessary funds, both intramurally and extramurally, in this area. Our record has been equally impressive in emergency funding in the past, in such areas as toxic shock syndrome and Legionnaire's disease.

AWARDS TO FOREIGN SCIENTISTS

Question: From time to time constituents write to raise questions about the awarding of research grants to scientists. In fiscal 1982 we understand NIH awarded 212 grants to foreign scientists for a total of $13.3 million. How much will you award to foreign scientists in fiscal 1983 and in what areas of research?

Answer: Since the current fiscal year is not yet completed, we cannot state precisely the number of awards that will be made to foreign scientists. However, we would not expect either the number of awards or the total obligations to differ substantially from prior years: 191 awards for $10.0 million in 1979; 207 awards for $11.1 million in 1980; 237 awards for $13.2 million in 1981; and, as you have stated, 212 awards for $13.3 million in 1982.

Research that is being funded through foreign grants in 1983 includes such areas as tropical diseases and epidemiological studies involving unique populations.

Question: Why would you send scarce research dollars abroad when we have a large corps of excellent scientists to choose from here at home -- and we already interact with foreign scientists through the Fogarty International Center?

Answer: In purusing its research objectives, the NIH recognizes the opportunities for furthering research programs through the use of unusual talents, resources, populations, and environmental conditions in other countries which are not available in the United States or which augment or complement existing resources. The NIH supports research in other countries only when such research has important specific relevance to the objectives of the NIH as authorized in the legislative and appropriation acts of the Congress.

NIH grant awards are based on the scientific excellence and program relevance of the proposed research activity. Thus, it follows that a foreign institution or international organization that meets these critera should be eligible for support in the interest of improving the health of all people. On the other hand, NIH does not view itself as responsible for enriching the research environment abroad in the same sense as it is charged to do so domestically. Thus foreign institutions are not eligible for grants for program projects, centers, resources, or National Research Service Awards, nor is indirect cost reimbursement provided in the vast majority of cases. Furthermore, grants may not be made to individuals in a foreign country.

Question: What special review requirements are placed on scientific applications from abroad to assure we fund only those of the highest merit?

Answer: All foreign grant applications undergo the same peer review for scientific merit required for domestic awards. National Advisory Councils are directed to consider in their deliberations whether a foreign application is of special importance in fulfilling the mission of the awarding unit. In addition, the application must fall within the upper half of the Council or Board priority score ratings as recommended for approval for that review cycle. These policy requirements are intended to ensure that research supported in foreign countries is of the highest caliber with significant relevance to problems of human health in the United States and abroad.

ORGANIZATIONAL STUDY

Question: Former Secretary Schweiker advised the Committee that he is undertaking a study of the organizational structure of NIH. In his January 21 letter the then Secretary said the study results "will provide a basis for focusing future discussions on possible changes" in the organization of NIH. Please tell us what the ex-Secretary and the Department have in mind with regard to the study.

Answer: The objective of the study, which is being conducted by the National Academy of Sciences' Institute of Medicine (IOM), is to develop the rationale and criteria to be met to determine the need for change, in any substantial manner, in the organizational struc-

ture of the NIH. A review of the NIH's organizational evolution and development will be conducted including an examination of factors involved in past change and the underlying rationale for the current structure. The NIH's approach to those issues which cut across organizational lines will be reviewed and alternative approaches suggested. In light of scientific developments and economic conditions, criteria to be met to guide major organizational change will be developed.

Question: To what extent is the study, which we understand might last more than a year, designed to head off proposals for separate Arthritis and other Institutes?

Answer: The IOM will issue its report 18 months after the initiation of the study, which is scheduled to begin in April 1983. The NIH believes that its current organizational structure should remain unchanged until the study is completed and the study recommendations are made widely available for review. The study is not designed to head off proposals for additional Institutes, but to provide a set of criteria--concurred in by the biomedical research community, the Congress, and the Administration--to guide the consideration of such proposals. Once these criteria are in place, proposals for additional Institutes (or other major organizational change), irrespective of their origin, can be considered in a rational and systematic fashion.

Question: Since Congress fell short of enacting the study which Mr. Schweiker wants done, what is your authority for carrying out the inquiry?

Answer: Section 513 of the PHS Act confers upon the Secretary contract authority to conduct evaluation studies. Also, the Director, NIH, has authority to execute contracts as the head of a procuring agency. (Congress has authorized GSA to procure goods and services for the benefit of the government, and this authority has been delegated to Executive Departments and to agency heads designated by Department Secretaries.) In addition, 5 USC 305 directs Department Secretaries to review systematically the operations of each of their organizations to determine the degree of efficiency and economy in their operations.

Question: What will be the cost of the study -- and from where will the money come?

Answer: The study, at a cost of $792,000, would be supported through the NIH Program Evaluation set-aside, as authorized by Section 513 of the Public Health Service Act. These funds generally support studies that are used to assist in program development and management decisions by examining program structure and function to determine how effectively the program mission is being accomplished.

Questions Submitted by Senator William Proxmire

BIOASSAY PROGRAM

Question: Dr. Wyngaarden, an article which appeared earlier this year in the Journal of Fundamental and Applied Toxicology has

raised some serious questions concerning the Bioassay Program. As you know, this Program tests various compounds for their ability to cause cancer when fed over long periods of time to mice and rats. The author claims that the test, which was designed years ago by the National Cancer Institute, was never validated properly and is very expensive. For example, the article states -- and I quote: "The design of this bioassay appears to have been created out of the best thoughts of several committees and reflects the opinions of the committee members. It is suggested that a drastically different design is needed and that such redesigning will require proper validation."

The article goes on to state: "As long as it is considered to be useful in detecting human carcinogens, this very expensive and time consuming procedure will continue to drain the toxicological resources of society. This report questions its usefulness and suggests that it is time to seriously consider alternatives." The article appears to substantiate a report issued around the same time by the National Research Council of the National Academy of Sciences which concluded that such tests are not only much more expensive but require several months, and that quick, inexpensive tests are already available to identify chemicals that cause mutations. Can you comment on these findings?

Answer: We are aware of the article which appeared in the Journal of Fundamental and Applied Toxicology. NIEHS scientists have prepared a brief yet critical response to the article. We understand that the response will be published in a future issue of the journal. These NIEHS scientists found numerous distortions and errors in fact which would lead one to question the significance of the entire article. A copy of the NIEHS response is attached, and I ask that it be made part of the record.

The NRC report is concerned with testing methods to identify chemicals that cause heritable mutations. It carefully (and properly) avoids issues surrounding the use of short-term tests to predict chemical carcinogenicity - either for rodents or for humans. Therefore, the report does not substantiate the JFAAT article referenced. The two documents deal with two distinct toxicological issues. It is true, as stated in the NRC report, that inexpensive tests are available to identify mutagens (chemicals that cause mutations). However, all mutagens are not carcinogens, and all carcinogens are not necessarily mutagens. So, the ability to identify mutagens does not provide a simple shortcut to identify carcinogens.

The application of short-term test results in the decision-making process leading to selection of chemicals for in vivo carcinogenicity testing is the aim of a large number of individuals and organizations, both in the federal government and in the private sector. Largely as a result of the coordination of testing resources by the NTP, the opportunity now exists to incorporate short-term test results more directly into the evaluation process. The NTP's commitment to this is demonstrated by the Program's extensive efforts in developing, validating, and applying short-term test methods to the evaluation of chemicals.

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Response to
"Lifetime Feeding Study in Mice and Rats - An
Examination of Its Validity as a
Bioassay for Human Carcinogens"
(Salsburg, 1983)
by J.K. Haseman, J. E. Huff, and J. A. Moore.

In a recent issue of Fundamental and Applied Toxicology David Salsburg (1983) published the latest in a series of papers (1977, 1980, 1981, 1982) critical of two-year carcinogenesis studies in rodents. This paper, like its predecessors, contains distortions and errors in fact that require response. The four major "shortcomings" of rodent carcinogenicity studyes as perceived by Salsburg are given below, followed by our comments.

I. "There are apparent inconsistencies" in how bioassay results are interpreted. The increase in tumors of a specific type is declared the 'casus belli' for designating one compound carcinogenic but is ignored in other cases" (Salsburg, 1983, p.64).

Salsburg (1983) cites data from three NCI studies as an example of inconsistency in the interpretation of bioassay results--uterine tumors in female F344 rats administered 1,5-naphthalenediamine (NCI, 1978a), Clonitralid (NCI, 1978b) or 2-(chloromethyl)pyridine hydrochloride (NCI, 1979). According to Salsburg, all three chemicals produced significantly increased incidences of uterine tumors, but only one was regarded as a carcinogen.

The incidences of uterine endometrial stromal polyps as reported in these studies are summarized below:

	Tumor Incidence			Statistical Significance (as reported by the NCI)	
Chemical	Control	Low	High	High Dose Effect	Trend
1.5-Naphthalenediamine	2/24(8%)	14/49(29%)	20/48(42%)	.003	.003
2-(Chloromethl)pyridine Hydrochloride	3/20(15%)	6/50(12%)	13/50(26%)	NS	NS
Clonitralid	0/19(0%)	2/41(5%)	6/44(14%)	NS	.036

The original report regarded the increased tumor incidence observed in the animals administered 1,5-naphthalenediamine as a chemically induced effect. The slight increases observed in the other two studies were reported as not related to chemical administration.

Salsburg claims to have found a "significant dose-related increase in uterine tumors" (p.64) in the female rats exposed to 2-(chloromethyl) pyridine hydrochloride. This is simply not true. Salsburg further states that there is a "highly significant (p 0.001) dose-related increase of uterine tumors" in the Clonitralid study. Again, the data fail to support his claim.

The data in the Clonitralid report include four additional uterine tumors in the high dose group: one metastatic carcinoma whose primary tumor site was the stomach; one hemangiosarcoma and one endometrial stromal sarcoma (both in a single animal); one squamous cell carcinoma. The metastatic carcinoma, hemangiosarcoma and squamous cell carcinoma are biologically unrelated to uterine stromal polyps and can not be combined for interpretative purposes. The endometrial stromal sarcoma can be combined, but this single additional tumor in the high-dose Clonitralid group has minimal impact on the statistical significance reported above (high dose effect: NS; trend: p=0.022). The only way we can reproduce Salsburg's P 0.001 trend is to base the statistical analysis on all uterine tumors, each assumed to occur in a separate animal and to carry out an uncorrected Cochran-Armitage test (NCI employed continuity-corrected methodology).

Thus, for the data cited as examples by Salsburg (1983), there is in fact no inconsistency in interpretation. The clearly positive effect was regarded as chemically induced; the negative and marginal effects were regarded as artifacts.

The discrepancies and misinterpretations cited above lead us to be concerned regarding the validity of other more general analyses summarized in Table 2 of Salsburg's (1983) paper. Were biologically unrelated tumors combined, or were multiple tumors in the same animal "double counted" as was done in the example given above? Salsburg apparently did not rely on the NCI statistical analyses nor does he give any evidence that the decision rules used in his calculations closely approximate the scientific judgment process (see Haseman, 1983b)

II. The sensivitity of the rodent carcinogenesis assay is low for the detection of human carcinogens. Of the 26 putative human carcinogens listed by Tomatis et al. (1978), "only 12 (46.2%) have been shown to cause cancer in rats or mice after chronic exposure by feeding or inhalation. Thus the lifetime feeding study in mice and rats appears to have less than a 50% probability of finding known human carcinogens. On the basis of probability theory, we would have been better off to toss a coin" (Salsburg, 1983, p.64).

Salsburg's "coin flip" analogy would be meaningful only if the "negatives" were true negatives rather than reflecting the fact that these chemicals simply had not been tested at all or were tested inadequately in mice or rats. That is, with the possible single exception of arsenic, none of Salsburg's alleged "negatives" were adequately tested by the oral or inhalation route in mice or rats at the time the Tomatis et al. (1978) article was published. Thus, it is inappropriate to regard these chemicals as showing no evidence of carcinogenitiy in mice or rats. Indeed, Salsburg's "negatives" include industrial processes such as underground hematite mining, for which no meaningful laboratory animal experiment is possible. One might more accurately state the result as follows: with the possible exception of arsenic, all of the Tomatis et al. (1978) putative human carcinogens adequately tested by the oral or inhalation route in mice or rats were indeed found to be carcinogenic.

Furthermore, the list of putative carcinogens used by Salsburg is out of date. There have been several more recent compilations of known or suspected human carcinogens (IARC, 1979; Althouse et al., 1980; IARC, 1982). In IARC's latest evaluation (1982), certain chemicals in the original Tomatis et al. list (oxymetholone, phenytoin, aflatoxins, chloramphenicol, cadmium and cadmium compounds) are now regarded as showing "limited" evidence of carcinogenicity in humans.

The new IARC document (1982) lists 7 industrial processes and occupational exposures and 23 chemicals or groups of chemicals that "are casually associated with cancer in humans." Of the 23 chemicals, only three were not supported by carcinogenic effects in laboratory animal experiments: (1) arsenic and arsenic compounds (experimental animal data "considered inadequate to make an evaluation"), (2) conjugated oestrogens ("tested in only one experiment in rats by oral administration. The data were judged insufficient to evaluate their carcinogenicity"; IARC, 1982, p.180) and (3) treosulphan ("no data were available" for evaluation; IARC, 1982, p.246). In all other cases there was either sufficient or limited evidence of carcinogenicity in laboratory animals.

Thus, there is clearly a strong positive correlation between known human carcinogens and adequately designed laboratory animal carcinogenicity studies, indicating a high level of sensitivity of the rodent studyies for the detection of human carcinogens. As a revealing point of fact, at least seven known or "probable" human carcinogens (aflatoxin, 4-aminobiphenyl, bis(chloromethyl) ether, diethylstilbestrol, melphalan, mustard gas and vinyl chloride) were shown first in experimental animals to cause cancer (Tomatis, 1979).

III. In addition to having a low sensitivity, the currently designed bioassay "produces so many contradictory answers as to suggest a very poor specificity" (Salsburg, 1983, p.66). "It appears most of the compounds that have been found to <u>increase</u> certain kinds of tumors actually <u>decrease</u> the incidence of other sorts of tumors" (Salsburg, 1982, pp. 181-182).

Undeniably, two-year carcinogenicity studies produce both increases in tumor incidence. However, rather than abandoning two-year carcinogenesis studies altogether, a more prudent course of action is to investigate the patterns of tumor decreases and attempt to identify possible causal factors, as well as to better characterize the biologic process or processes responsible for these opposing responses. One such factor is mentioned by Salsburg: survival differences. Another is decreaed weight gain. In many studies the decreased incidences of certain endocrine and reproductive system tumors (notably mammary gland fibroadenomas in female F344 rats) are clearly related to decreased weight gain in the dosed groups (Haseman, 1983a). Gries and Young (1982) found a similar correlation between reduced body weight and decreased incidence of pituitary tumors in Wistar rats. These findings are not surprising since a number of published reports (e.g., Ross and Bras, 1971; Rowlatt et al., 1973; Roe and Tucker, 1974; Tucker, 1979; Conybeare, 1980) have indicated that dietary intake (and hence weight gain) is inversely correlated with spontaneous tumor incidence in rodents.

We are not aware of any published data that show increases in tumor incidence associated with decreased body weight.

Haseman (1983a) also found an inverse correlation between the incidences of liver tumors and leukemia in F344 rats for which there is no obvious underlying mechanism. The point is that if one examines the decreased tumor incidences more closely, certain patterns of tumor incidence and possible explanatory factors emerge. While more research is needed, it would certainly be premature to conclude that this problem invalidates the two-year carcinogenicity study and that "a drastically different design is needed."

IV. "The lifetime feeding study has never been subjected to proper validation as an assay for human carcinogens" (Salsburg, 1983, p.63).

A formal series of validation studies were not included as part of the original NCI design of the two-year bioassay in the late 1960's. More importantly, however, human carcinogens have subsequently been tested in a number of two-year feeding or inhalation studies in laboratory animals and these chemicals are invariably found to be carcinogenic. Recent examples are the inhalation studies of vinyl chloride (Drew, et al., 1983) and asbestos (McConnell et al., 1982). Further, the National Toxicology Program is implementing experiments with other human carcinogens, which will allow better evaluation of the adequacy of the $B6C3F_1$ mouse and F344 rat models for human carcinogenic hazard and risk assessments.

To put Salsburg's criticisms in some perspective, the scientific value of the two-year carcinogenesis study in laboratory animals is well-recognized by respected national and international bodies, such as the World Health Organization, the National Academy of Sciences, the International Agency for Research on Cancer, the Chemical Industry Institute of Toxicology, and the Office of Technology Assessment of the U.S. Congress. For instance, the IARC concluded that "in the absence of adequate data in humans it is reasonable, for practical purposes, to regard chemicals for which there is sufficient evidence of carcinogenicity...in animals as if they presented a carcinogenic risk for humans." OTA states that "the testing of suspect chemicals in laboratory animals...is the backbone of carcinogen identification."

Despite Salsburg's opinion to the contrary, we doubt that anyone familiar with carcinogenicity data would be persuaded that it is necessary to resort to "a drastically different design." Neither do we think the two suggestions made by Salsburg (a return to the 12 month study of the 1960's; a factorial design with the suspect compound and a known promoter) are likely to gain widespread acceptance as general screening methodologies. What we do believe is that one should recognize the limitations of the two-year carcinogenicity study in rodents, and devote resources and research efforts to any problem areas that are identified. Further, in our opinion efforts to detect and evaluate chemical carcinogens need to be expanded through the collection of data on dose response, chemical disposition patterns, genetic toxicity, other (non-tumor) dose related toxicity, etc. These data, when evaluated with the results of the more common two year studies will permit a better understanding of the carcinogenesis process and the relationships between the results of two-year cancer studies in laboratory animals and human health.

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FUNDING FOR BIOASSAY PROGRAM

Question: What is the total amount spent on the Bioassay Program since its inception, and how much do you propose to spend next year?

Answer: The Bioassay Program accounts for approximately 75% of the National Toxicology Program funded by NIEHS. From the beginning of the Bioassay Program in FY 1979 through FY 1982, $164 million has been spent. We estimate that $48 million will be spent in both FY 1983 and FY 1984.

Question: What percentage of your budget is spent on these long term feeding tests?

Answer: Approximately 19% of the Bioassay Program is spent on the long-term feeding studies.

ACQUIRED IMMUNE DEFICIENCY RESEARCH

Question: The March 28 issue of Time magazine carried an article on Acquired Immune Deficiency Syndrome (AIDS) indicating some scientists were complaining that NIH has been "dragging its heels" about awarding $4 million set aside for AIDS research. Dr. Michael Lange of St. Luke's Hospital in New York City referred to your failure to distribute these funds as "a disgrace." Do you have any comment on these charges?

Answer: We are not certain how Time Magazine arrived at the figure of $4 million, but it probably refers to responses received from a Request for Applications (RFA) issued in August 1982 by the NIH to stimulate research relating to AIDS and Kaposi's sarcoma. In response to the RFA, NIH received 43 applications, which would have cost a total of about $4 million if all had been funded. Thus, some appear to have concluded that NIH is "withholding" that amount of money.

When the RFA was first issued, the National Cancer Institute expected to expend $1.25 million to fund projects stemming from it. In fact, NCI and the National Institute of Allergy and Infectious Diseases (NIAID) will spend $2.8 million in FY 1983 to fund 10 projects stemming from the RFA. Of the 43 applications received under the RFA, 11 were disapproved by a special study section that reviewed them as a part of the NIH peer review system. Most of the rest were not eligible for funding because they received low priority scores.

Many in the outside community infer that this one RFA is the only route to funding on AIDS. This is certainly not the case. NIH will issue a second RFA in May 1983 to encourage applications on causative agents in AIDS, and it is expected that NIAID and NCI will spend a total of $2 million in 1984 to fund projects submitted in response to this new RFA.

Moreover, NIH has many other mechanisms for receiving and funding projects on AIDS. It is estimated that NIH will spend approximately $9.6 million directly on AIDS in fiscal year 1983 and about $12.5 million in fiscal year 1984. I should also mention that the NIH is building on a science base of approximately $200 million in related research in FY 1982 alone.

CENTRALLY FURNISHED SERVICES

Question: Dr. Wyngaarden, I notice that the increase in the amount assessed for the payment of centrally furnished services

varies from Institute to Institute. For example the Institute of Dental Research will increase those payments by 6.5 percent in 1984 while the Institute of Allergy and Infectious Diseases will have to pay an additional 7.9 percent. Can you tell us what causes these variations?

Answer: Payment for the various research support services provided centrally to the NIH Institutes is based on specific factors related to each Institute's use of those services. Such factors include the number of positions allocated to each Institute, intramural research funds applicable to each Institute, grant and training funds available to each Institute, and hospital beds assigned to each of the Institutes. It is these factors that are used in determining each Institute's payment for the centrally furnished services, and the year-to-year changes in these factors alter the proportion that each Institute provides as payment.

PERCENTAGE OF AWARDS FUNDED

Question: Provide for the record the percentage of its awards each Institute is able to fund and tell us which Institute funds the highest percentage of its awards, which the lowest percentage, and the reasons for the difference.

Answer: For 1984, the award rates for the various Institutes are estimated as follows:

Institute	1984 Request
NCI	30%
NHLBI	31
NIDR	48
NIADDK	30
NINCDS	32
NIAID	26
NIGMS	38
NICHD	33
NEI	41
NIEHS	39
NIA	19
NIH	31%

As shown above, the National Institute of Dental Research is expected to have the highest award rate in 1984, while the National Institute on Aging will have the lowest award rate.

In 1984, as in prior years, the differences in award rates are the result of several factors, including: the number of applications estimated to be received; the number estimated to be approved for funding; prior year commitments in noncompeting awards; the total resources available to fund grants; the basic structure of the Institute (e.g., little or no intramural program, centers, training); the "mix" of research project grants and the vastly more expensive program project grants; anticipated increases in average costs; and new opportunities in particular research areas.

INTRAMURAL RESEARCH BUDGETS

Question: I'm curious as to how you put together your budgets for intramural research at the various Institutes. For example you are requesting $135,000 for within grade pay increases for the National Institute of Allergy and Infectious Diseases, with 479 intramural positions, while the National Institute of Neurological and Communicative Disorders and Stroke with 155 fewer positions would receive $221,000 for within grade salary increases and would also receive more money for 1982 pay raise costs. Why is that the case?

Answer: There will be differences among the Institutes in the components of their intramural budgets because of the many factors that comprise the total estimate. These include the range of salaries of the personnel, their time in grade, and the types of appointments and positions [e.g., general schedule vs. commissioned officers and physicians (M.D.'s) vs. laboratory investigators (Ph.D.'s)].

NATIONAL CANCER INSTITUTE

STATEMENT OF DR. VINCENT T. DeVITA, JR., DIRECTOR

ACCOMPANIED BY:

DR. JAMES B. WYNGAARDEN, DIRECTOR, NIH
JOHN P. HARTINGER, FINANCIAL MANAGER, NCI
NORMAN P. MANSFIELD, DIRECTOR, DIVISION OF FINANCIAL MANAGEMENT, NIH
ANTHONY ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET, DHHS

BUDGET REQUEST

Senator WEICKER. Next, we will hear from the National Cancer Institute which administers the largest budget of all the Institutes of NIH. The revised fiscal 1984 budget for NCI is $986.6 million, or $2.5 million less than the January budget and only $3 million above the fiscal 1983 level.

Here to testify in support of the NCI budget is Dr. Vincent T. DeVita, Jr., Director of the Institute.

Dr. DeVita, we welcome you and your staff. Please go ahead and introduce the people with you.

Dr. DEVITA. Thank you, Mr. Chairman.

On my left, we have Mr. John Hartinger who is the Budget Officer for the National Cancer Institute.

And, of course, Dr. Wyngaarden and Mr. Itteilag are on my right.

I would like to give a skeletal version of my statement, Mr. Chairman, in the interests of time. The National Cancer Institute's mission is to reduce the incidence, mortality and morbidity from cancer through the support of basic research and the application of the results of basic research. When the National Cancer Act was passed in 1971, it provided the resources for both.

As Dr. Wyngaarden has already intimated, the revolution in biology that has taken place in the last decade—mapping genes, cloning genes, and the discovery of oncogenes, which I would like to return to in a moment—was in no small measure a part of the introduction of the resources from the national cancer program.

The application of the results of research, or what I call the effector arms of the Institute, were unique to the National Cancer Act. These are the expanded clinical trials program, cancer centers, cancer control and community activities, and expanded training programs for cancer physicians.

It has taken us about a decade to get this instrument in the trim shape it is in now. And we have both progress and promise for more progress as a result of application of results of research in three areas:

Prevention. We know cancer is preventable as a result of studies in the last decade. We have now initiated prospectively about 20 clinical trials, attempting to interfere with the late stages of carcinogenesis.

We believe that we will be able to determine, before the end of this decade, whether we will prospectively be able to reduce the incidence of cancer in some common tumors like cancer of the colon, cancer of the breast.

We know cancer is curable; 46 percent of the population with serious cancers in this country are surviving for 5 years.

We now see decreases in national mortality in people under the age of 45 with cancer, where it is the most common disease killer. We have sent data to you on that.

Interest in diagnosis is also heating up because we have monoclonal antibodies and other very interesting new tools that were not here a decade ago like nuclear magnetic resonance scanning.

We are facing a paradigm change in the 1980's that is related to discoveries in the laboratory, especially since the discovery of oncogenes. The products of these oncogenes may in fact turn out to be useful targets in the diagnosis, prevention, and treatment of cancer.

All this, the amalgamation of the support for basic research and the application of results of basic research, is really what has brought molecular biology to the bedside, and makes a very interesting challenge for those of us at the NIH who have to move the resources around in order to make sure that the opportunity for the application of the results of these efforts in basic research in fact are taken.

Mr. Chairman, our budget request for 1984 is $986,681,000. That concludes my statement.

I would be happy to answer questions.

BUDGET REQUEST

Senator WEICKER. $986 million would be at the same level as 1982, roughly; right?

Dr. DEVITA. Yes.

Senator WEICKER. The 1982 level.

Dr. DEVITA. The 1982 level was $943 million, Mr. Chairman. The 1983 level was $983,576,000.

The difference, Mr. Chairman, is a transfer of the bioassay program, from NCI to NIEHS. That is probably the difference between $943 million and your figure.

COMPETING RESEARCH GRANTS

Senator WEICKER. All right.

I would like to get a perspective on how the revised budget for fiscal year 1984 affects your Institute.

How many additional new and competing grants will you get above the January budget? And what further research will you be able to do as a result?

Dr. DEVITA. The difference is between 544 new and competing grants in the original budget, and 817 new and competing grants in this budget.

As Dr. Wyngaarden indicated, that allows us to put more money into our research project pool whch has always been the Institute's No. 1 priority. This is where many of the discoveries that I have mentioned came from.

AVERAGE COST OF GRANTS

Senator WEICKER. Now, as indicated earlier, there is going to be a difference in the average award for new and competing grants below what the full average costs would be for new grants. This appears to be a difference of $17,800, $142,400 full cost versus $124,600 in the revised budget.

How do you think that is going to affect the recipients and the work?

Dr. DEVITA. It will result in some budget tightening.

Senator WEICKER. Well, the budget tightening is here.

Dr. DEVITA. Individual budget tightening depends on what they are able to accomplish under the proposed grant application. In other words, we are awarding less than recommended, but——

NUMBER OF GRANTS

Senator WEICKER. If you had your druthers, what would you rather have? Would you rather have more projects at less than full funding or fewer projects at full funding— if you had your druthers?

Dr. DEVITA. Mr. Chairman, we have debated the issue of numbers versus full funding a great deal. And I must say there are arguments on both sides of the issue.

The advantage of the stability at the numbers level is that it is a message that we are stabilizing the support for basic research in terms of the numbers of people who continue to conduct the research. But there is a limit to what we can do with numbers alone.

Senator WEICKER. That's what worries me about this. I am only asking your professional judgment. I am now trying to put it in the context which won't be injurious to any of the persons representing the various Institutes.

That is, assuming the same dollar figure for comment—we won't get into a head-on with the administration—I am only asking your professional judgment as to how you would like to have those dollars arranged.

I am all for sending messages, but I also want them to be honest messages. And if the message is we have more people participating, that may sound great to the guy in the street, but you have a little greater perception as to what the problem is than the average layman. So that's why I ask the question.

And I will ask it of everyone who appears from the various Institutes. If you had your druthers, would you rather have full funding for fewer? That still is within the discretion of the Congress working with the administration.

I realize that there is a certain political simplicity to the message that we have got 5,000. You know, that sounds great.

Was it Thoreau's comment: "The question is not are we busy, but what are we busy about?"

And that is really the essence of my question as to these 5,000. Would you if you had your druthers prefer fewer, but at full funding?

Dr. DEVITA. We believe it is not possible to continue to support some research projects at less than full funding. Some types of research are very expensive, and there is no question individual judgments have to be made about support of research projects at full funding.

Senator WEICKER. So your feeling is there might be differences within this spectrum where some should get full funding?

Dr. DEVITA. Well, some of the work on oncogenes I referred to is so exciting, and represents such an important leap forward in terms of our practical application of the results, that I feel in these areas, research should be funded at full level.

Obviously, a tradeoff has to be made. These kinds of judgments are being made every day. All of them are painful. But they do require individual adjustments.

Senator WEICKER. Well, I hear that term used all the time. But when your fellows stand before us, it is not as painful as the people suffering from the disease.

In this town, when one says, "Well, it is a terribly painful decision," it is not, understand, a comparable kind of pain to the other, which is real.

Is it true, then, that in terms of the various grants, there would not be a set dollar amount per grant, but rather that within that, you will also exercise discretion to where something may be considerably down from, using my figures, $12,400, whereas something else would run at full cost?

Dr. WYNGAARDEN. Yes. Senator, that has been practiced for some time.

The adjustments you indicated are average adjustments. Some projects are not negotiated down at all.

CANCER CENTERS

Senator WEICKER. Now, in the statement, in order to achieve these additional numbers in the grant area, as I indicated in my statement, which I believe is based on the presentation made to us, there will be major cuts in continuation and discretionary grants in research centers, applied research.

My next question, then, is these competing grants are not out there by themselves. At least, as I think of them. Maybe, based on your answer, they are out there by themselves.

What I am saying is: What does the cutting in these other areas do to the totality of the project of which competing grants, at least in my opinion, are a part?

Dr. DEVITA. Well, I sincerely believe——

Senator WEICKER. Do they relate, these other activities, to what is going on out there in the competing grant area?

Dr. DEVITA. Yes, indeed, they do, Mr. Chairman. Take, for example, the center grants. By our estimate, one-third of the center core grants supply resources that would normally be required under the RO1/PO1 research grants. In other words, they are offsetting the cost of those grants by supplying core resources. So they in fact are related to one another.

Senator WEICKER. Well, that sort of poses a problem, then, doesn't it, in terms of bottom-line result? Has a thing been said in terms of result design? It is sort of taking from Peter to pay Paul in that sense.

Dr. DEVITA. Yes; as I indicated in my brief opening statement, the essence of the cancer program that was created in 1971 by the Cancer Act was both support of basic research and the application of results of basic research. We have tried to maintain a proper balance between the two.

It is never easy, even in the best of times, to maintain this balance, knowing what to invest in the applications and what to invest in basic research. But our first priority has always been to support the basic research program.

COMPETING CANCER CENTERS

Senator WEICKER. I have here an NIH document which indicates the research center schedule for competing renewals, in fiscal year 1984, in which funding would be eliminated.

It says, NCI Cancer Research Centers, and it says, Note: Based on priority score, 16 of the following would not be funded: Bowman Gray Hospital; University of Southern California; Salk Institute; Howard University; Northwestern University; University of California, Los Angeles; Roswell Park Medical Center; University of North Carolina; New York University Medical College; Yale; M. D. Anderson Hospital; University of Texas, Galveston; St. Jude Hospital; University of Vermont; Michigan Cancer Center Foundation; University of Arizona; Dartmouth University; Purdue University; University of Iowa; and La Jolla Cancer Research Foundation.

Is this accurate?

Dr. DEVITA. That is the list of the center core grants that will be competing in 1984, Mr. Chairman.

APPLICATION OF RESEARCH RESULTS

Senator WEICKER. We have seen recent news accounts which seem to raise hopes for important breakthroughs in the field of cancer research. One noted cancer researcher was quoted by the New York Times as looking for "the end of cancer before this century is over."

The same article indicates that you may feel this is not an outlandish statement. Tell us a little more, if you might, about this optimism and again, about the oncogenes which scientists apparently think play a role in the cancer process.

Dr. DEVITA. The statement, I believe, was made by Dr. Lewis Thomas who is not given to frivolous statements. Dr. Thomas is looking at the pace of discoveries in biology, referring to discoveries like the oncogenes, where we now are able to map 15 to 20 genes that were first identified in cancer viruses and now found to be present in normal people, as apparently normal genes. He notes that we are now getting right down into the steps of the carcinogenic process.

When you are getting in that close, it is not outlandish to assume that one should know the mechanism of the causation of cancer in our lifetime; the prevention of the disease should not be too far behind.

There has been a lot of argument in the scientific community about the step that we are measuring. The oncogene is probably a last step because of the assay system we have.

From the practical point of view, the last step is probably the first one we want to discover because it has more applicability. So we are very excited about using the information on oncogenes in some practical way.

My guess is within the next 2 years, we will know how practical the use of the oncogene products will turn out to be because they are being synthesized even as we speak. One of our very finest scientists, a world-renowned scientist, is synthesizing the protein products, the materials these genes make, which probably make the cell turn from normal to malignant.

Once we have these products in hand, we can attack the product, prevent its production, identify cells that are making it, and so forth.

It is the kind of thing dreams were made of in 1970, but it is a reality today. And that is what I believe Dr. Thomas meant in making his prediction and I meant by saying it is not an outlandish statement.

ACQUIRED IMMUNE DEFICIENCY SYNDROME

Senator WEICKER. Relative to the two matters, the AIDS syndrome—and how do you pronounce K-a-p-o-s-i-s?

Dr. DEVITA. Anyway you like, sir. I pronounce it Kaposis. Some pronounce it Kaposis. Some pronounce it Kaposhis. Kaposis is the more common usage.

Senator WEICKER. All right. The AIDS, at least as has been indicated to me by counsel, syndrome has also been associated with Kaposi's sarcoma which is a form of cancer. What role are you playing in the effort to combat this disease? What progress do you have?

Do you consider the money you are spending on the AIDS problem sufficient?

Dr. DEVITA. Well, we are funding every project we can studying the AIDS problem. Our budget has gone from a 1982 level of $2 million to a 1984 level in the range of $5 to $6 million.

It is a very important syndrome. This apparent accident of nature offers a lot of information we need to know about because it is both a public health problem and we are seeing an unusual cancer arise in this population afected with AIDS which by itself is not a malignant cancerous growth.

The main AIDS syndrome is an immune deficiency syndrome, but the unusual cancer associated with it offers us an opportunity to identify some causation between a presumed agent that is causing it, probably a virus, and a cancer.

A lot of laboratories are scrambling around the country as fast as they can to establish the facilities to be able to study AIDS. Part of the problem is getting the molecular biologists to the bedside where the patient with the tissue that has to be studied is residing.

PREPARED STATEMENT AND SUBMITTED QUESTIONS

Senator WEICKER. Doctor, thank you very much. I have further questions for response to the record.

Again, I could probably sit here and go on with you for a lot longer, but we have some time restraints.

I would appreciate responses for the record to some additional questions.

Dr. DEVITA. Thank you, Senator.

[The information follows:]

Statement of Dr. Vincent T. DeVita, Jr.

I am pleased to have this opportunity to discuss the progress and accomplishments of the National Cancer Institute. You have heard of the revolution that is occurring in the biomedical sciences. Support for cancer research in the National Cancer Program played a major role in this exciting change. Scientists working with new technologies are daily reporting research advances. Some of these represent potential paradigm changes--approaches to understanding prevention, diagnosis and treatment of cancer that are radical departures from the past.

Support of basic research is and always has been our highest priority. But now more than ever before, it is important to look ahead, to develop mechanisms for moving those advances that are ready into studies that may eventually benefit people. We have been planning since 1980 to assure that this process will occur at an appropriately measured rate. We now have effector arms--mechanisms for testing, in human populations, ideas that come from basic research--for all of our programs that need them.

I will discuss our programs in the major research thrusts in terms of a continuum that begins with basic research and moves through human studies, and ends with the dissemination of findings into our communities.

The data that we collect continuously from our Surveillance, Epidemiology and End Results (SEER) Program show 46 percent of Americans survive the serious cancers 5 years, and many of them can be considered cured. National mortality from cancer is falling for Americans below age 45 and would be falling for all age groups if it were not for lung cancer--a largely preventable disease. The fall in national mortality is due primarily to advances in the treatment of cancers of the breast, ovary, testes, the lymphomas, and leukemias, among others. The decreases in mortality have occurred in the face of level or only slightly increasing incidence rates. These data mark the steady progress made and confirm that cancers are curable diseases.

Prevention of Cancer

Cancers are also preventable diseases. It is possible to reduce cancer rates by removing substances that either initiate or promote the cancer process. The time it takes to see an effect may be surprisingly short (6 months) or it may be as as long as 20 years. We believe we can begin to drive the incidence of cancer down in some cases in less than a decade. Here are some of the reasons:

- Epidemiologists linked estrogen replacement medication with an increased incidence of uterine cancer among postmenopausal women. The FDA issued a warning and physicians followed by reducing prescriptions. Within 6 months the incidence of uterine cancer had diminished. Estrogens are a known promoter for uterine cancer.

- Data from the 1982 Surgeon General's report on the health consequences of smoking show that a smoker's cancer risk approaches that of a non-smoker's after several years of cessation. The rate at which this happens varies for different cancer sites from 4 years for

esophageal cancer, 10 years for cancers of the head and neck, and 20 years for lung cancer. These data show that persons exposed to carcinogens are not inevitably "fixed" to get cancer.

Our emphasis on basic research in prevention over the past 10 years has yielded a critical mass of information with potential application for people. Perhaps most exciting is the information on chemopreventive agents, or antipromoters, that inhibit the later stages of cancer causation. In laboratory studies these substances can halt or reverse the development of cancers already initiated by cancer-causing agents (carcinogens). Many antipromoters occur naturally in the diet: vitamin A, its chemical cousins the retinoids and its precursor beta-carotene, vitamins C and E, and selenium.

What has not been completed are prospective studies to see whether these substances are effective in humans. Such studies in small, defined populations are necessary to allow us to see the potential impact of a prevention strategy before it is systematically applied to the entire U.S. population. Through our reshaped cancer control program, we have initiated such clinical studies in prevention. These studies started in 1982, and we should be able to determine by 1990 whether some types of cancer can be prevented by adding antipromoters to the diet. For the most part, the substances we are testing are readily available, inexpensive and non-toxic when taken properly.

The chemoprevention program is possible now because we have in place all necessary components: testable hypotheses; effective agents; a sufficient number of trained cancer specialists (including clinical trial and nutritional science experts, pharmacologists, epidemiologists and biostatisticians) to develop and conduct the studies; and the SEER Program to monitor the results.

Another area of opportunity we will explore further this year is biochemical epidemiology. This approach uses biochemical and molecular biological approaches to identify persons at risk to cancer. As one example, scientists have developed a test so sensitive that it can tell whether minute amounts of a carcinogen have been "taken up" by a person and incorporated into their tissues--actually bound to the DNA in their cells. DNA is believed to be the point of attack for most carcinogens that initiate the cancer process. By incorporating this and other tests into epidemiologic studies of populations that are potentially exposed to cancer-causing agents because of their work or lifestyle, it may be possible to identify individuals who have been "initiated" and might be candidates for intervention trials with antipromoters.

Improving Cancer Treatment

For many years, NCI has supported clinical trials through cooperative groups and cancer centers. The clinical trials program has been molded and modified since 1974 and is the effector arm for cancer treatment. In addition, clinical training programs have yielded a cadre of cancer specialists practicing in communities across the country. And this has given us a unique opportunity to integrate clinical trials with the practice of cancer medicine and to diffuse advances in treatment as they are being developed.

NCI's Community Clinical Oncology Program, or CCOP, is designed

to reach the 80 percent of cancer patients who are still treated in their home communities. The CCOPs will integrate the many specially trained community physicians with cancer centers and the large cooperative groups that conduct treatment studies. We now are evaluating some 200 applications submitted in response to our request for applications.

In addition, we are disseminating the latest information on established cancer treatments to community physicians through a new computerized cancer information system. The PDQ data base provides information in a user-interactive format. It draws on computerized lists of experts and clinical investigators to tell physicians who is doing what and where within a geographic matrix. This final link in the NCI's clinical treatment effort offers the promise of rapidly decreasing national mortality with existing treatments by closing the gap between what we know we can do and what we actually do now.

Progress in cancer treatment is evident. Development of cancer drugs and better therapeutic X-ray equipment, added to what surgery can accomplish, has improved survival for seven major forms of cancer and decreased cancer mortality for Americans under age 45. Still, the treatments for cancer are complex and undergoing constant remodeling. Some clinical research opportunities we are currently supporting are:

- taking advantage of exciting new data that may allow us to circumvent the major cause of treatment failure with drugs; we may have uncovered the initial steps cancer cells take to bypass the effects of anticancer drugs.

- discovering new drugs for the treatment of cancer through NCI-funded drug discovery groups--think tanks of academic and industry scientists; they will assure that cancer drug development keeps pace with modern molecular biology. These programs will use new, more specific targets identified at the molecular level to construct drugs.

- testing monoclonal antibodies and other biologics in selected cancer patients;

- establishing equipment for cancer radiotherapy using beams of neutrons, as a potential improvement upon standard X-irradiation used with radiosensitizers and radioprotectors; and

- comparing CT scanning and ultrasound with nuclear magnetic resonance--a new diagnostic technology that produces three-dimensional images with electromagnetic fields rather than X-rays.

Opportunities from Cancer Research

Support of investigators who develop basic research ideas takes almost 40 percent of our annual budget. This is because laboratory research on the biology of cancer provides the underpinnings for future programs that will directly benefit people. And we have many areas with potential for payoff.

One example is the area of research concerned with RNA tumor viruses. Pieces of the puzzle started falling into place when scientists studying RNA viruses isolated oncogenes. Although oncogenes occur in normal cells, they are regulated by normal cellular mechanisms. But when put under the control of RNA viruses, the oncogene

can cause cancer. We've seen this in laboratory animals and in cultures of cells grown in the laboratory. We know now of about 15 such genes that exist in all cells of your body and mine.

The latest experiments implicate this set of oncogenes in human cancer. Last year. NCI grantees from three different institutions independently isolated oncogenes from human bladder, lung and colon cancers. These genes were able to change normal mouse cells to cancer cells.

Still other research in the virus area indicates that oncogenes are associated with chromosome rearrangements that characteristically occur in nearly all patients with certain forms of lymphoma and leukemia. In the case of Burkitt's lymphoma, the rearrangement appears to activate an oncogene.

These studies suggest that a limited set of genes, occurring normally in all of us, can be corrupted and deregulated to trigger cancer-like changes. Research is advancing rapidly. We should soon know what role the oncogene plays in cancer causation and whether it is involved in a final common pathway. This is very exciting. We've never before had information that pointed to a final common pathway in cancer causation. We also should know whether we can use other new technology to find and attack the protein products produced by oncogenes as a form of diagnosis and treatment. The new cancer drug discovery groups will pay close attention to this area.

In another area, we are watching with growing concern a puzzling new disease called Acquired Immunodeficiency Syndrome (AIDS). We just recently approved funding for new grants and supplemented others to study AIDS. Epidemiologic studies to date have failed to reveal a cause for the spectrum of diseases represented by AIDS, including a rare cancer, Kaposi's sarcoma. The incidence of AIDS is increasing at an almost geometric rate. Almost half of the patients have died. It is an urgent problem, and research into this syndrome could yield important new information on all types of human cancer.

Finally, I know this Subcommittee is interested in the first RNA human cancer virus isolated by one of our intramural scientists. It originally came from the cancer cells of an American man with T-cell leukemia. We know cases of this uncommon form of cancer tend to cluster in certain rural regions of Japan and in the Caribbean. Last year, the NCI scientists successfully cloned the human T-cell leukemia virus (HTLV). This opens the door to definitive studies that may provide a basis for developing a prevention strategy for certain human cancers. For example, it may be possible to develop a vaccine that could be used in the limited populations where the virus tends to cluster. This technique was ultimately successful in eradicating smallpox.

I have told you of our current accomplishments and our plans for the following year. We are rich in ideas because the resources supplied to the National Cancer Program put many outstanding scientists to work in the 1970s. We now have in place a mechanism to translate those findings that are ready into studies aimed at widespread application. We will continue looking over the horizon, planning for the next decade. Such planning in science means the ability to make abrupt, mid-course adjustments--pursuing those areas that appear to be ready for application; phasing down those that have served us well

but are less vital to advancing the biological and clinical revolution. These efforts were geared toward making the National Cancer Program a well-trimmed ship, able to change direction quickly as we continue to find new ideas for the prevention, treatment and control of cancer.

Mr. Chairman, the request for the National Cancer Institute for Fiscal Year 1984 totals 986,681,000. This is an increase of $3,105,000 over the 1983 estimate. I would be pleased to answer questions and to supply additional information for the record.

Biography of Dr. Vincent T. DeVita, Jr.

Name: Vincent T. DeVita, Jr., M.D.

Date & Place of Birth: March 7, 1935; Bronx, New York

Education:

1957 - B.S. (Chemistry) College of William and Mary, Williamsburg, Virginia

1961 - M.D. (With distinction) George Washington University School of Medicine, Washington, D.C.

Positions Held:

1961-62: Internship, University of Michigan Medical Center, Ann Arbor, Michigan

1962-63: Residency in Medicine, George Washington University Medical Service, District of Columbia General Hospital, Washington, D.C.

1963-65: Clinical Associate, Laboratory of Chemical Pharmacology, National Cancer Institute, Bethesda, Maryland

1965-66: Senior Residency in Medicine, Yale-New Haven Medical Center, New Haven, Connecticut

1966-68: Senior Investigator, Solid Tumor Service, Medicine Branch, National Cancer Institute, National Institutes of Health, Bethesda, Maryland

1968-71: Head, Solid Tumor Service, Medicine Branch, National Cancer Institute, National Institutes of Health, Bethesda, Maryland

1971-74: Chief, Medicine Branch, National Cancer Institute, National Institutes of Health, Bethesda, Maryland

1974-80: Director, Division of Cancer Treatment, National Cancer Institute, National Institutes of Health, Bethesda, Maryland

1975- Clinical Director, National Cancer Institute, National Institutes of Health, Bethesda, Maryland

1980- Appointed by the President, Director, National Cancer Institute, National Cancer Program, National Institutes of Health, Bethesda, Maryland

Academic Appointments:

Associate Professor of Medicine, George Washington University School of Medicine, Washington, D. C., 1971-75
Professor of Medicine, George Washington University School of Medicine, Washington, D.C., 1975-

Editorial Boards:

Associate Editor, Journal of the National Cancer Institute, Bethesda, Maryland, 1968-74
Scientific Editor, Cancer Chemotherapy Reports, National Cancer Institute, 1970-74
Advisory Editor, Journal of Radiation Oncology, Biology, and Physics, 1975 -
Associate Editor, Editorial Advisory Board, Cancer Research, 1977-81
Member, Board of Medical/Scientific Consultants, Cancer Nursing, 1978-80
Member, Board of Scientific Council, Cancer Chemotherapy and Pharmacology, 1977-
Associate Editor, Cancer Clinical Trials, 1977-
Associate Editor, Cancer Investigation, 1983-
Member, Editorial Board, Amer. Federation of Clinical Oncologic Societies, 1977-78
Member, Editorial Board, American College of Physicians (A.C.P.) Audio Cassette Program, 1979-1980
Member, Editorial Board, Seminars in Oncology, 1979-84
Associate Editor, The American Journal of Medicine, 1978-1981
Member, Editorial Advisory Board, Breast Cancer Research and Treatment, 1980-
Member, Editorial Board, Your Patient & Cancer, 1980-
Member, Editorial Board, Gynecologic Oncology, 1981-
Member, Editorial Board, Hematological Oncology, 1981-
Member, Editorial Advisory Board, Physicians' Drug Alert, 1982-
Member, Editorial Board, Journal of Clinical Oncology, 1982 -

Committees and Other Offices:

Councilman, Assembly of Scientists of the National Cancer Institute, National Institutes of Health, 1968-70
Chairman, Program Committee, American Society of Clinical Oncology, Inc., 1972
Clinical Research Committee, NCI
Board of Directors, American Society of Clinical Oncology, 1973-76
American College of Surgeons Commission on Cancer, Committee on Patient Care and Research, 1975-
Advisory Committee on Clinical Investigations II - Chemotherapy and Hematology, American Cancer Society, Inc., 1975-76
Publications Committee, American Society of Hematology, 1975-
WHO Expert Advisory Panel member, 1976-
Board of Directors, American Association Cancer Research, 1976-79
Lasker Award Jury, 1976-
President, American Society of Clinical Oncology, 1977-78
Chairman, Treatment Committee of the French-American Agreement 1976-
Chairman, Special Membership Committee, American Association for Cancer Research, 1978-79

Member, Panel of Consultants on Clinical Oncology, International Union Against Cancer, 1979-82

Specialty Board Certification:

Diplomate of the National Board of Medical Examiners, 1961
Diplomate of the American Board of Internal Medicine, 1968
Diplomate in the Subspecialty of Hematology, American Board of Internal Medicine, 1972
Diplomate in the Subspecialty of Medical Oncology, American Board of Internal Medicine, 1973
Recertification, American Board of Internal Medicine, 1974

Professional Societies:

Fellow, American College of Physicians
American Medical Association
American Society of Hematology
American Society of Clinical Oncology
American Association for Cancer Research
American Federation for Clinical Research
American Society for Clinical Investigation, elected May, 1972
Society of Surgical Oncology (Ewing Society), 1976-1979

Honors and Awards:

Alpha Omega Alpha Medical Honor Society
Smith-Reed-Russell Medical Honor Society
Tobacco Research Industry Fellowship, Mount Desert Island Biological Laboratory, Bar Harbor, Maine, 1959
Award by the Government of Peru, "Oren del Sol en el Grando de Official," 1970
Visiting Professor of Medicine, Stanford University School of Medicine, July, 1972
Albert and Mary Lasker Medical Research Award, November, 1972
First Annual Clowes Lecture, Roswell Park Memorial Institute, October, 1973
DHEW Superior Service Award, 1975
Esther Langer Award, June 1976
Alumni Medallion, College of William and Mary, October 1976
Jeffrey Gottlieb Award, November 1976
Karnofsky Prize, 1979
Griffuel Prize, Association for the Development of Research on Cancer, Paris, December 1980
James Ewing Award, The Society of Surgical Oncology (The James Ewing Society) Marco Island, Florida, April, 1982
Honorary Doctor of Science Degree, The College of William and Mary, Williamburg, Virginia, May, 1982
Alumni Achievement Award, The George Washington University, February, 1983
Honorary membership, Society of Gynecologic Oncology, January, 1983
Honorary membership, Japanese Cancer Society, February, 1983
Honorary fellow, American College of Radiology, April, 1983

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Questions Submitted by the Subcommittee

NEW BUDGET FOR 1984

Question: We would like to get your perspective on how the revised NIH budget for FY 1984 affects your Institute.

How many additional new and competing grants will you get above the January budget -- and what further research will you be able to do as a result?

Answer: We support the Administration's efforts to fund 5,000 grants, and find that the budget presented here today allows us to do that. This budget will also allow us to fund our highest priority research. The current budget plan would enable the National Cancer Institute to fund 817 new and competing research project grants, which is 273 grants above the original budget request of 544 grants. These additional grants enable the NCI to emphasize research in cause and prevention, treatment and cancer biology.

Question: Under your budget revision, the average NIH noncompeting grant award is projected to decrease by about $12,400 below what the full average cost would be ($143,100 full costs vs. $130,700 in budget revision). How will this affect your Institute -- and to what extent will it change the scope and quality of the projects that are reviewed by your study sections?

Answer: Noncompeting research project awards for the National Cancer Institute would be reduced an overall 10.8 percent from recommended levels including both indirect costs and direct cost reductions taken in FY 1984 and prior years. On the average, the full costs of the noncompeting grants would be $169,800, and the budget level would be $151,500 - a reduction of $18,300 per grant. Even with this reduction when compared to the study section recommended average, the 1984 budget includes an increase in the average cost of noncompeting awards over 1983.

The reductions in noncompeting grants from study section levels actually have no effect on competing applications and it is difficult to predict what effect these reductions will have when grantees apply for future renewal grant support.

Question: To what extent will any clinical trials be affected by the proposed cuts in research and development contracts and cooperative clinical research?

Answer: The contract mechanism is used primarily to support targeted development of new means to treat cancer. For example, the National Cancer Institute Drug Development Program, which is charged with the discovery and development of new drugs is supported primarily through the contract mechanism. In addition, the developmental efforts for new biological agents and for new technologies in the field of radiotherapy, including radiosensitizers and radioprotectors, are also supported through contracts. All of these efforts are geared toward providing the physician with new tools in treating cancer patients. The assessment of these new tools (whether they be new drugs, new

biological agents, or new equipment for diagnosis or treatment), is conducted through clinical trials. The reductions in contracts will therefore result in delays in the development of these new tools and their introduction and assessment in clinical trials.

Question: The new budget proposes to eliminate the 5% stipend increase for predoctoral and postdoctoral training, to make further reductions from the January budget in the number of trainees, and to decrease the number of research career awards to promising scientists. What effect will these steps have on your Institute's training program -- and what effect will it have on young people contemplating careers in biomedical research?

Answer: The number of trainees supported under the National Research Service Awards program did not change as the budget was revised. The National Cancer Institute's training program is the major source of the highly qualified scientists who will be needed to solve the cancer problem. Because the research trainees presently beginning training will require from three to eight years to become independent cancer researchers, the impact of reductions in the FY 1984 budget will not be known until much later. Astute young people can consider seeking training under other NCI research mechanisms such as the clinical education program, and for more advanced trainees, the research career programs.

The elimination of the 5 percent stipend increase should not affect decisions made by serious trainees to pursue research careers, as this increase amounts to an average of only $560 per year per trainee.

In the career programs, we will still be able to support the most meritorious awards and in fact will provide funds for two new programs, the Preventive Oncology Award (K07) to capitalize on cancer prevention activities, and the Physician Investigator Development Award (K08) to persuade M.D.'s and D.O.'s (Doctors of Osteopathy) to pursue careers in surgical oncology, radiation oncology and preventive oncology.

FUNDING FOR GENERAL CLINICAL RESEARCH CENTERS

Question: To what extent will the proposals to reduce funding for general clinical research centers and biomedical research support grants affect biomedical research in general and your Institute's work in particular?

Answer: The proposals to reduce funding for general clinical research centers (GCRC) and biomedical research (BRS) support grants were two reductions necessitated by the decision to fund 5,000 new and competing renewal research project grants within the same total dollar level as in the January budget.

The proposal to reduce the funding for GCRC awards by $2,021,000 would allow the Division of Research Resources to maintain funding for all 74 of the existing centers, although at a reduced level, by careful negotiation of each center award. As a result, there would be some reduction in the core support that the centers provide to investigators working on NIH supported research project grants. In 1982 the GCRC provided the clinical

research environment for principal investigators who hold a portfolio of 1,298 NIH-supported research grants valued in excess of $200 million.

The work of the National Cancer Institute would be affected by the proposed reduction in GCRC funding. In 1982 more than 189 National Cancer Institute supported research grants costing over $30 million relied upon the trained staff, research beds, equipment and clinical environment provided by the GCRC to carry out cancer research efforts.

The Biomedical Research Support (BRS) grant program awards funds to research institutions based on their level of Public Health Service (PHS) research grants support. These funds complement or supplement project grants by providing for pilot research, support of new investigators, centrally shared instrumentation, interim support and emergency funding. In FY 1982, BRS funds were used to support nearly 9,000 of such research activities of 516 grantee institutions. The proposed reduction in the BRS grant activity of $24,657,000 would result in a 52 percent reduction in the average size of all BRS awards. As such, 52 percent of research activities at the institutional level that are currently supported by BRS awards would have to find other sources of funding.

The work of the NCI would be affected by the proposed reduction in BRS funding. In 1982 more than 428 NCI supported research grants costing over $48 million were awarded to Institutes which also relied upon the flexible funding provided by the BRS award mechanism to supplement or complement their research efforts aimed at cancer research.

REDUCTION IN NCI CANCER CENTERS

Question: The new budget for NCI proposes to reduce centers support by about $19.8 million.

How many of the 53 centers the administration proposes to drop are comprehensive or other types of cancer centers -- and what are the implications of this for health research?

Answer: During FY 1984, 20 centers will be competing for renewal of their core grants. Six of the 20 are centers recognized by the National Cancer Institute as Comprehensive Cancer Centers and a number of the other 14, primarily clinical, are comparable in size and importance. The 20 centers are:

Wake Forest University, Bowman Gray School of Medicine, Winston Salem, North Carolina
University of Southern California, Los Angeles, California
Salk Institute, La Jolla, California
Howard University, Washington, D.C.
University of California at Los Angeles, Los Angeles, California
Roswell Park Memorial Institute, Buffalo, New York
University of North Carolina, Chapel Hill, North Carolina
New York University Medical College, New York, New York
Yale University, New Haven, Connecticut
M.D. Anderson Hospital, Houston, Texas
Dartmouth College, Hanover, New Hampshire

La Jolla Cancer Research Foundation, La Jolla, California
Northwestern University, Chicago, Illinois
University of Texas Medical Branch, Galveston, Texas
University of Vermont, Burlington, Vermont
Michigan Cancer Foundation, Detroit, Michigan
University of Arizona, Tucson, Arizona
Purdue University, West Lafayette, Indiana
University of Iowa, Iowa City, Iowa
St. Jude Children's Research Hospital, Memphis, Tennessee

It is widely known that cancer centers are of significant importance to the research efforts of the Institute, and as such NCI will do everything feasible to fund as many of these centers as possible within available funds. Consideration will be given to several factors in reaching those decisions including priority score and geographic distribution. In addition, funds will be stretched as far as practical through negotiations with grantees.

Question: The center grants are regarded as the "glue" that holds centers together and makes it possible for them to coordinate their laboratory and clinical work on cancer. If this core support is removed or reduced, where will they get funds to continue -- by raiding the money available under regular NIH research grants?

Answer: It is reasonable to expect that if support to centers institutions are reduced, that the costs for other research grants may increase.

CLINICAL EDUCATION

Question: The new budget proposes to reduce clinical education awards by about $2 million. What effect will this have on the effort to assure that medical schools are aware of the latest techniques in treating cancer?

Answer: The Clinical Cancer Education Program grants have contributed significantly to the scope and quality of cancer education in medical and dental schools and affiliated hospitals, and in developing and maintaining multidisciplinary cancer teaching activities which would not exist otherwise. This is the only federal program which provides a means for disseminating, in a cohesive fashion, the latest advances in cancer prevention, diagnosis, and treatment to medical, dental, and nursing students and to practicing physicians. It also provides students with the opportunity to learn cancer research methodology working with faculty mentors on both laboratory and clinical projects.

The program has recently been revised to meet newly emerging needs in cancer education. The new program guidelines will emphasize the dissemination of cancer control and treatment, rather than provide funds for the support of trainees. The current budget plan would enable the National Cancer Institute to fund 79 Clinical Cancer Education grants, which is 26 less than the original budget request of 105 grants, but only five less than in 1983.

TREATMENT RESEARCH

Question: The new budget will provide you with about $6 million more for cancer treatment research than did the January budget. What will this additional money be used for?

Answer: The increase will provide additional funding for research grants. Such an expansion in grants will have many important results. It will, for example, permit increased support of new approaches to chemotherapy, based on an increasingly sophisticated understanding of the mechanism of action of anticancer agents at the cellular level. Instead of relying largely on the random screening of various chemical structures for antitumor activity, what such work may allow is the rational design of new agents with increased selectivity for cancer cells and, therefore, decreased toxicity to important normal cells.

With most standard chemotherapeutic agents, initial or acquired resistance to the cytotoxicity of the drugs poses a severe limitation on clinical usefulness. Further grant work on mechanisms of drug resistance and techniques to circumvent such resistance is a very high priority both at the laboratory and the clinical level. Also, more grant research with biological response modifiers promises to introduce a degree of selectivity into cancer treatment not previously possible with other kinds of systemic treatment. In addition to the potential offered by monoclonal antibodies, other promising avenues include certain virally affected human tumor cell lines (so called viral oncolysates), with which preliminary results in small exploratory trials have been encouraging.

Combination chemotherapy has yielded very promising early results in certain epithelial cancers such as those of the head and neck and esophagus. These areas would benefit greatly from increased support; the head and neck area, in particular, is one in which expanded multimodality trials in previously untreated patients, done in a cooperative fashion by several institutions, are likely to show an impact on the natural history of these neoplasms.

ONCOGENE RESEARCH

Question: What can you tell us about "oncogenes" which scientists apparently think play a role in the cancer process by being switched on at the wrong time and producing too much protein, causing uncontrolled growth of cells?

Answer: "Oncogenes" are units of information within normal cellular DNA of all species which seem to control important cell functions. The activity of "oncogenes" was first recognized when they were captured by viruses and were then shown to cause cancerous changes in recipient cells. The "oncogenes", about 20 of which are known, can be considered to be integral and central to our understanding of cancer. A number of events can potentially activate these oncogenes. For example, chemical carcinogens, other agents which promote the development of cancer, or various molecular "on" switches could activate these genes. Once active, the oncogenes produce a product which interacts with the cell to generate many changes in those cells.

Secondary products, such as new antigens and enzymes, proteins that we only see in development, and a loss of normal control are regularly observed. It is important to note that the activation of oncogenes can occur by cellular changes such as chromosomal breakage and abnormal rejoining, or by viruses which themselves do not contain oncogenes, but in either case, the activation results in tumor formation. The protein product of the oncogene can either be abnormal, or it can be produced in excessive amounts for the cell in question, so as to make a cell behave in an abnormal manner. It will be critical to understand how the oncogene-coded protein functions and how it can be turned off. Because it is a protein, specific antibodies can be made to it. These antibodies, which can be monoclonal in composition, could be useful for diagnosis by recognizing that oncogene activation had taken place. Such a test would be much more specific than some of the present early diagnostic tests which detect cell products which were generated second-hand after the oncogene activation. Alternatively, the antibodies to the oncogene product could be used in treatment if this product will be accessible to the antibody. Previously, antibodies were made to some of the secondary products made as a response to the oncogene protein. Such secondary products could be turned off but the cell was still a tumor cell. However, because the product of the oncogene itself is the key to subsequent events, we know that the turning off of oncogenes will result in a normal cell. Alternatively, if the cell does not turn off the oncogene, the cell could be killed by antibody specific to the oncogene product. Accordingly, we feel that the knowledge of oncogenes and their functions represents one of the strongest leads for the understanding of cancer as well as its prevention and treatment.

MONOCLONAL ANTIBODIES

Question: In your present arsenal of anti-cancer weapons, how much importance do you attach to "monoclonal antibodies" which are designed to seek out and destroy malignant growths without causing damage to normal cells?

Answer: Monoclonal antibodies have several advantages when viewed as potential anti-cancer agents: they can be produced in unlimited quantities; they can be altered biochemically to improve their efficacy; and they have some specificity for the cancer cell. The latter advantage makes monoclonal antibodies distinct from previous forms of cancer treatment in that the degree of specificity for the cancer cell as opposed to normal cells is much greater. It is already apparent that monoclonal antibodies can be injected intravenously in man and will be tranported to sites of cancer involvement. Although they may attach to certain normal tissues, the degree of attachment to malignant tissues is far greater. Thus, it is likely that these reagents will prove useful as carriers for cytotoxic agents and may under certain conditions be useful themselves as anti-cancer biologicals.

Monoclonal antibodies represent a major advance in biological research and preliminary results in animal tumor models and in man seem to indicate that they will be very useful in the diagnosis and treatment of cancer. Early clinical studies are under way to explore monoclonal antibodies and their conjugates. Preliminary results indicating beneficial

therapeutic activity are already appearing in the scientific literature. Thus, we believe that monoclonal antibodies will provide an important advance in cancer treatment in the coming years.

RAISING HOPES ABOUT CANCER

Question: We also are interested in your research on interferon and cancer caused by viruses. What progress are you making in these areas?

Answer: The three types of interferon (alpha, beta, and gamma) are all in clinical trials. These interferons can be extracted from normal lymphocytes after appropriate stimulation or can be made by genetic engineering. Therapeutic activity is being seen with alpha interferons in melanoma, renal carcinoma and particularly in lymphoma. Toxicity studies have been done to define the tolerable dose in man and the side effects of these materials. Broad testing is now being carried out to determine the range of therapeutic effects when used as a single agent and subsequent trials are planned adding interferon to other anti-cancer modalities. Very early clinical studies are beginning with beta and gamma interferon and it is anticipated that by the end of 1983, and certainly during 1984, the range of therapeutic effects for all three types of interferon will be much better defined. While the interferons are not active anti-cancer agents in all types of cancer, it seems evident that they will have efficacy in certain cancers. Their role, when integrated with other forms of therapy, remains to be defined.

The past decade has seen a remarkable revolution in research on biological carcinogenesis. Work done during the first half of this century suggesting a viral etiology of certain animal cancers was confirmed by later investigators who isolated tumor viruses from a wide variety of animals including rodents, birds, cats, amphibians, and primates. It was logical, therefore, that scientists should focus on the search for viruses that might be involved in human cancer in the same way as the viruses responsible for cancer in lower animals. The advent of powerful and highly sophisticated techniques for detection and analysis of specific nucleic acid sequences and the proteins they code for has shown that the role of viruses in malignancy is more complex than was previously thought. It is likely that viral information, present in genes of apparently normal human cells and replicating with them, is intimately involved with the development of cancer. Triggered by chemical carcinogens, radiation, hormones, the aging process, and other influences, these sequences may direct the synthesis of the proteins responsible for malignant transformation of the cell. For this reason, tumor viruses are now regarded as important tools for deciphering the molecular pathways by which a normal cell is transformed into a malignant one. The isolation of viral proteins responsible for malignant transformation and the identification of the genetic sequences that code for them have placed reproducible means by which the molecular mechanisms of cancer can be scrutinized at the disposal of the research scientist. Moreover, the discovery that some of the most potent cancer viruses derive the information coding for their transforming proteins from normal cells by genetic recombination provides a unique opportunity to isolate and analyze cellular genes involved in tumorigenesis.

NCI scientists have discovered a growth factor, termed T-cell Growth Factor (TCGF), which for the first time allows routine growth in the laboratory of white blood cells (T-cells) which are important for the immune response. These cells are critical for fighting infection and for fighting cancer cells.

A surprising but very important "spin off" from these studies by the same NCI scientists was the discovery that when cells from adult patients with a particular kind of leukemia or lymphoma of T-cells were treated with TCGF, the T-cells released viruses of the kind (type-C retroviruses) that cause leukemia and lymphoma in many animal systems. The virus is called human T-cell leukemia-lymphoma virus (HTLV) and is one of the first examples of a virus associated with human cancer. It has now been isolated from seven different patients and extensively characterized. Very recently the NCI team succeeded in the molecular cloning of HTLV.

World-wide epidemiological collaboration is now underway among NCI scientists and investigators in Japan, Jamaica, South America, the People's Republic of China, England, France, Israel, and Italy. The NCI group has determined that HTLV is specifically associated with a form of adult T-cell malignancy relatively common in the Orient, the Carribean, parts of South America, and possibly certain areas of the Middle East. Possible future practical benefits from the HTLV include the following: (1) With further epidemiological virological studies, the mode and means of virus transmission may be identified. It may be possible to prevent disease by avoiding infection with the virus. There is also the future possibility of vaccination against the virus in the high risk regions of the world, but much more study in this regard is needed. (2) Unraveling the mechanism of how HTLV causes cancer at a molecular level might lead to new biological approaches to the treatment of cancer. (3) Finally, it appears that some patients with the deadly new syndrome called AIDS (Acquired Immunodeficiency Syndrome) may have evidence for HTLV infection. This finding may help us understand the cause of AIDS and how to prevent its spread.

One widespread human virus, Epstein-Barr virus (EBV), has been very strongly implicated as a contributing cause of Burkitt's lymphoma and nasopharyngeal carcinoma, malignancies found predominantly in African and Asian populations, respectively. Evidence has recently been accumulating that EBV in immuno-depressed American populations may be a factor in the development of malignant lymphomas.

A series of sero-epidemiological studies have implicated herpes simplex virus type 2 as a possible cause of carcinoma of the uterine cervix. An *in situ* cytological hybridization technique for detection of virus-specified nucleic acid sequences has been developed, and the technique has demonstrated that a significant portion of neoplastic cervical tissue specimens was positive. In contrast, viral nucleic acid sequences were only rarely detected in sections of normal cervical epithelium. Equally exciting is the recent preliminary finding that cytomegalovirus DNA is present in human tumors such as Kaposi's sarcoma, prostate adenocarcinoma, and colon carcinoma.

The strong epidemiological evidence that hepatitis B virus (HBV) is associated with the development of primary liver cancer in man has recently been supported by results utilizing the techniques of molecular biology. These techniques have shown that there are multiple copies of HBV nucleic acid sequences in liver tumor cells grown in culture. It has also been demonstrated that viral DNA sequences are usually present in liver tumors from patients who are positive for the HBV surface antigen. However, in a different line of human liver tumor cells, considerably less HBV genetic information was present, suggesting that in certain circumstances hepatomas can lose HBV genetic sequences after transformation. Thus, these sequences may not be required for the maintenance of the transformed state. In addition, there is evidence that the chronic HBV carrier also having the presence of antigens to HBV may indicate increased risk of future development of hepatoma.

THE "AIDS" EPIDEMIC

Question: We all have been very concerned about the wave of deaths from Acquired Immune Deficiency Syndrome, (AIDS). The often fatal ailment has been associated with Kaposi's Sarcoma, a form of cancer.

What role are you playing in the effort to combat this disease—and what hope of progress do you have?

Answer: In fiscal year 1982, the National Cancer Institute spent $2.4 million on research directly associated with the Acquired Immunodeficiency Syndrome (AIDS) epidemic. Thus far in fiscal year 1983, NCI has awarded, or will soon award, grants -- which are responses to NCI's Request for Applications (RFA) -- for a total of $1.8 million, as well as supporting contract and intramural research. Under the same NCI RFA, the National Institute of Allergy and Infectious Diseases will support over $1 million of research. NCI plans to spend a total of $4.4 million in fiscal year 1983 specifically for the AIDS epidemic. For fiscal year 1984 the NCI is issuing a request for cooperative agreements applications from interested investigators for both basic and applied studies designed to determine the etiology of AIDS and its associated aggressive generalized form of Kaposi's Sarcoma (KS). The determination of etiology may make possible the development of appropriate methods for eventual prevention and/or control of the disease. The RFA will be published in May in the NIH Guide for Grants and Contracts and the application receipt date will be in August, 1983. A four-year period of performance is anticipated with a total funding of $1,000,000 (NCI) for the first year. The types of research projects that might be funded include: direct in vivo and in vitro efforts at isolation, identification, and characterization of the causative biological agent; analysis of human tissue with appropriate tests indicative of the presence, state of integration, and location of viral or pro-viral DNA, or other infectious forms; recognition and identification of marker antigens of pathognomonic significance; cytogenetic analysis for chromosomal changes that relate to disease induction; and in vitro search for direct morphological transformation and/or cytopathology of appropriate target cells.

The NCI has assumed a leading role in efforts to combat

AIDS. There exist sufficient observations to suggest that this syndrome may involve viruses and/or other infectious agents and therefore it is appropriate to initiate a comprehensive series of investigations on the etiology of this syndrome in order to determine the best method(s) of prevention. The involvement of an aggressive form of Kaposi's Sarcoma with AIDS, the general observation that many cancers are related to changes in the immune system, and the communicable nature of the syndrome explain NCI's strong interest. The increasing incidence of AIDS, the rapid and multiple observations on the nature of the syndrome, and the need for interaction of the investigators with each other and with the NCI demonstrate that these studies would best be carried out under the cooperative agreement mechanism.

A direct effort by NCI is the formulation of the AIDS Task Force which consists of an investigative group of NCI scientists who are attempting to establish a role and isolate a transmissible infectious agent from these patients. The scientific effort is headed by Dr. Robert Gallo of NCI, who had been the first to isolate a human tumor virus which is implicated in the induction of human leukemia involving the same type of retroviruses in the AIDS syndrome. This activity will take place both at NIH and the NCI-Frederick Cancer Research Facility (NCI-FCRF). FCRF is ideally suited because of existing containment facilities. A proportion of the technical support contract effort at FCRF is being oriented towards this investigation, exemplifying the concept of rapid deployment by contract mechanism to meet a new and pressing problem. An integration of the NCI's clinical and scientific activities in AIDS has been coordinated with the Task Force's contingent comprising the extramural cooperative agreements already in place or which are about to be instituted. The amount of this effort will entail about $500,000.

Within the broader mission, the NCI has been investigating the cause(s) of and risk factors for AIDS since May, 1981. This research effort has focused on characterizing the precursor of clinical AIDS in two groups at high-risk, homosexual men and hemophiliacs. By studying the very earliest signs of AIDS rather than clinically advanced cases, it has been possible to assemble large numbers of persons for epidemiologic analysis and to trace the natural history of the AIDS process. Results have documented a high proportion of AIDS-type immune abnormalities in apparently healthy individuals from these two groups. Epidemiologic analysis points to a sexually or blood-borne transmissible agent. Current efforts are directed toward delineation of specific risks for each group (e.g., types of sex practices, types of blood products), and toward early detection of AIDS patients by currently available laboratory or clinical tests with potential application to AIDS prevention. In addition, collaboration with laboratories expert in the characterization of transmissible agents is underway using samples from these preclinical patients who may be a useful source for tracking this putative agent.

A number of investigators are conducting clinical trials utilizing various modalities of therapy for all stages of Kaposi's Sarcoma (KS). These include chemotherapy, irradiation and treatment with biological response modifiers.

Some of the earliest studies of chemotherapy for epidemic

Kaposi's Sarcoma employed the same drugs found to be effective in the more indolent "classical" variety of this tumor. Patients with relatively non-invasive epidemic KS have been treated primarily with single agents and those with more aggressive disease have received combination chemotherapy using several drugs. All forms of the disease have been shown to be quite responsive to drug therapy with most patients demonstrating some regression of tumor. The major difficulty with this modality is that most cancer chemotherapy agents cause suppression of the bone marrow and therefore add an additional insult to the patient's already compromised immunological status. Newer studies of chemotherapeutic drugs are now concentrating on those agents which cause less bone marrow suppression. No results are yet available from these trials.

A second class of therapy employs irradiation. Investigators at the NCI have recently begun a study of total skin electron beam radiotherapy for patients whose disease is primarily cutaneous. Classical KS is known to be highly responsive to radiotherapy using conventional x-ray treatment. Unlike classical KS, which is generally localized, epidemic KS very often is widely disseminated. Electron beam irradiation has an advantage over more conventional types in that it penetrates the body only to very shallow depths and could therefore be expected to cause minimal disruption of the body's immune function, even though the entire body is treated. Again, there are as yet no data available, but the technique holds promise for controlling the spread of the cancer while permitting concomitant therapy aimed at immune restoration.

The third class of therapeutic studies involves attempts at immune restoration. The most widely studied agent is alpha interferon, which has shown definite activity in the hands of several investigators. Alpha interferon produced by recombinant DNA technology has been also used in the treatment of Kaposi's Sarcoma. These data from Memorial Sloan-Kettering Cancer Center, about to be published, show that complete remissions were achieved in three of the 12 cases treated, and partial remissions in several others. The underlying immune deficiency has not been improved with this treatment.

Other types of interferon are now or will soon be under active investigation around the country. Investigators at the University of California, San Francisco, are planning a clinical trial using the chemopreventive and differentiating agent beta-carotene. A number of other immunomodulators are also planned for study including thymosin, indemethacine, interleukin2, and cimetidine. The hope is that such therapy might restore the body's ability to "recognize" and reject the abnormal tissue compromising the cancer.

Since effective therapy or vaccine may be years away, the immediate need is for public health intervention efforts aimed at the high risk groups, such as education of homosexual men regarding AIDS risk factors and alteration of the policies regarding donation and processing of blood products.

"AIDS" RESEARCH FUNDING

Question: How much money are you spending on the AIDS problem -- and is it sufficient?

Answer: The National Cancer Institute supported a total of $2.4 million in the Acquired Immunodeficiency Syndrome (AIDS) research in 1982, plans to spend $4.4 million in 1983, and at least $4.7 million in 1984 with plans for an additional $1 million on viral isolation studies also in 1984. At the current time, these amounts are sufficient to address this increasingly threatening problem. However, the plans and directions of NCI are flexible enough to allow additional resources to be quickly redirected to this problem if the situation warrants.

In addition, NCI supports extensive immunological and virological research vital to understanding this immune dysfunction.

Question: To what degree do you coordinate your efforts with the Allergy and Infectious Diseases Institute and the Centers for Disease Control?

Answer: The National Cancer Institute has obtained cooperative input from both the National Institute of Allergy and Infectious Diseases (NIAID) and the Centers for Disease Control (CDC) to expedite its Acquired Immunodeficiency Syndrome (AIDS) activities. The NIAID will fund some of the approved applications received in response to NCI's first Request for Applications (RFA) (FY 1983) and the NIAID is fully cosponsoring the new NCI RFA concerned with the infectious etiology of the syndrome (FY 1984). NIAID staff and grantees will participate in an NCI AIDS "working group", which is designed to enhance exchange of scientific information and reagents and to expedite research progress. Additionally, CDC staff have participated in NIH workshops designed to clarify the epidemiology and research approaches to pursue, and NCI staff have obtained from the CDC biosafety staff specific recommendations concerning laboratory safety measures for inclusion in the NCI/NIAID RFA on infectious etiology. The Division of Research Safety of NIH has also been involved in formulating guidelines for laboratory workers in this area.

In addition to the NCI AIDS "working group", the recently established NCI AIDS Task Force is being helped by an Advisory Group of outside scientists with various forms of expertise. Members of the CDC as well as the NIAID effort units in AIDS are being invited to share in the scientific input and results so that mutual exchange to critical new information occurs as rapidly as possible.

ORGAN SITES

Question: Our Committee, as you know, directed you to continue funding for the Organ Site Program which focuses on cancers of the bladder, large bowel, pancreas and prostate. This matter has evoked some controversy between those who want to do the work through a series of task forces and those who wish to see the project made a regular part of the NIH peer review system.

Please bring us up to date on how you have responded to the Committee's directive.

Answer: After considerable discussion between the National Cancer Advisory Board and the staff of the National Cancer Institute, research supported under the Organ Site Program is continuing with some changes designed to make the program more efficient and cost effective, principally dealing with the administrative setup of the program. In 1984, a budget of $12 million has been provided for research which focuses on cancers of the bladder, large bowel, pancreas, and prostate.

Question: What position has the National Cancer Advisory Board taken on this matter -- and why all the controversy about it?

Answer: The National Cancer Advisory Board (NCAB), in an effort to gather needed information on the Organ Site Program, initiated a review of the program. Subsequently, it has made a number of recommendations for restructuring the program. Specifically, the NCAB has recommended that the National Cancer Institute (NCI) maintain a strong, multidisciplinary Organ Systems Program. To achieve this, they recommend that a single Organ Systems Coordinating Center (OSCC), external but coordinated with the NCI, be established through open competition. This OSCC will administer and coordinate the activities of each of five working groups targeted to the breast, bladder, large bowel, pancreas, prostate and any future sites that may be selected. These working groups will carry out program planning, develop and stimulate research initiatives, hold workshops and seminars in order to have extensive communications with the scientific and medical communities. The OSCC will develop criteria and guidelines to initiate and terminate working groups as needed. The NCAB further recommended separation of review from program activities within the program, and that funding should continue at a level approximately equal to that of the previous funding for the program if such funds are available. These recommendations were voted on by the NCAB at the May 19, 1982 meeting and reaffirmed unanimously at the meeting of February 2, 1983. The NCI has begun to implement these recommendations. A Request For Applications (RFA) has been issued for an open competition to establish an extramural OSCC.

Considerable controversy has arisen because of misperceptions which have led to misunderstandings and misinformation about the proposed changes. These changes concern the structure of the program, not support for the program. The proposed changes will maintain the extramural input that has been utilized in the past and will maintain special emphasis in each of the current organ site areas while maintaining rigorous review with the flexibility to add new organ site areas without the need to create new costly mechanisms. This will result in a more cost efficient operation. The NCI intends to continue strong support for the Organ Site Program.

Question: You have previously expressed concern about the costs of staffing and review at the institutions which house the organ site task forces. To what extent have those problems been resolved?

Answer: The National Cancer Advisory Board (NCAB) and the

NCI have reviewed the costs of staffing and review at the institutions which house the Organ Site Task Forces. Establishment of the new Organ Systems Coordinating Center, which should be operational by March 1984, should result in a significant decrease in administrative costs. This can be done while still maintaining a strong programmatic effort with extramural involvement and direction in each of the organ site areas.

PROTECTING THE INVESTMENT

Question: At a time when many budgets are going down, Congress has been increasing funding of the National Institutes of Health, including your Institute. We are concerned that these scarce resources be carefully and effectively used and that there be no basis for criticism of your management of this money.

What assurances can you give us that your Institute is making careful and effective use of the appropriations we provide you?

Answer: The National Cancer Institute has taken an aggressive management stance to assure that its appropriation is spent for the maximum benefit of the National Cancer Program. The ability to fund new initiatives in the forefront of science and to undertake applied research in cancer prevention and control depends on our achieving cost savings and reallocating resources.

These objectives have required a thorough examination of all of our activities and some very difficult resource distribution decisions. The decision making processes are public and involve the NCI Executive Committee, the Boards of Scientific Counselors of each of the NCI's operating Divisions, the National Cancer Advisory Board and the President's Cancer Panel. The NCI Executive Committee, composed of the Director, Deputy Director, Associate Directors, and Division Directors, considers and decides all major policy, program and management issues with the guidance of the outside advisory bodies.

The Boards of Scientific Counselors, whose members are non-government expert scientists, advise the Divisions on direction and emphasis within their programs. They can implement their policy advice through specific review of each concept for a contract or Request for Applications proposed by the Division. They are also responsible for site visits to our intramural laboratories and branches in which the quality and relevance of the science as well as the resources expended are reviewed in a way comparable to the review of extramural grant applicants. Thus, these Boards assist us in making resource allocation decisions for the intramural and extramural aspects of the research thrusts in which they are expert. Additionally, a Frederick Cancer Research Facility Advisory Committee reviews the contractor-initiated research at that site to assure that its quality is on a level with that of our intramural and extramural programs.

Overall, NCI business management systems including grants and contracts have been centralized in the Office of Administrative Management. The business management, review, and

program management of grants and contracts are in individualized organizational components to assure the rigor and integrity of each function. All research and development contract proposals are now merit reviewed by committees of extramural scientists. Since, 1980, the NCI Executive Committee has reviewed every existing contract and redirected over $40 million in contracting activity, primarily toward investigator-initiated research grants.

In conjunction with the advisory bodies, the NCI Executive Committee has given exhaustive consideration to grant funding mechanisms which would enable us to fund the highest possible number of approved applications by stretching available resources (by reducing the amount provided for a specific award) while not destroying the viability of the research. For the past two years, we have reduced grants from the level recommended by peer review groups in order to fund additional meritorious grants. Simultaneously, we have held NCI intramural research to a percentage increase no greater than that allowed for research project grants in order to preserve parity. The impact of budget constraints on the extramural community and ways to stretch dollars has been addressed in depth by the President's Cancer Panel.

Other internal management initiatives have included a review of every staff position in the Institute and reallocation of personnel ceilings to high priority areas in order to allow new program development such as control and prevention research. We have also achieved savings by relocating laboratories situated in rental buildings to the NIH campus or to the Frederick Cancer Research Facility.

The NCI has institutionalized mechanisms and attitudes which ensure future tight management of its resources. Our internal control systems and well established decision-making process will allow us to maximize scientific return on appropriations. A report on the management of the Institute was requested by the Committee and is in the final review process within the Department.

WASTE, FRAUD AND ABUSE

Question: Aside from the peer review system, what institutional arrangements do you have that serve to deter waste, fraud or abuse in the handling of federal funds?

Answer: In matters of waste, fraud, and abuse, the National Cancer Institute coordinates its activities centrally with other NIH organizations such as the Division of Management Survey and Review (DMSR), the Office for Protection from Research Risks (OPRR), and the Division of Research Grants (DRG). Within the National Cancer Institute, each grant or contract is assigned to a program director or project officer who reviews the proposal for appropriateness and compliance with existing regulations. In addition, progress reports are reviewed to assure that the work is being done in accordance with stated objectives. Finally, the Grants Administration Branch or the Research Contracts Branch undertakes a thorough review of all budget submissions and makes appropriate revisions when necessary. In the event any information is received which indicates improper use of

government funds, the DMSR is immediately consulted for the purpose of determining whether or not a formal investigation should be undertaken.

GENETIC ENGINEERING

Question: I know scientists are focused on manipulating genes as the great hope in cancer research. We also have heard much about using artifically produced antibodies as the helpmate to more conventional forms of cancer treatment.

Please bring us up to date on this promising research -- and tell us whether there is a real basis for the optimism we have been hearing about lately.

Answer: Recombinant DNA technology has resulted in a biological revolution. Today, one can isolate individual genes of interest and get them to be expressed not only in the laboratory, but also in intact animals. Most obvious of these are the experiments which show that the introduction of the gene for growth hormone into mice can be accomplished so that the growth hormone is overproduced, resulting in giant mice. Another example was that the gene of one species coding for the production of hemoglobin, an oxygen carrying protein in red blood cells, could be introduced into another species in a way that expression was detected. Some genes produce very small levels of potent biological protein products and can be made to produce the desired amount of product in bacteria. An example of this is alpha-interferon which was so produced. Treatment of cancer patients with recombinant DNA-produced interferon is ongoing in several laboratories with some success. A fascinating offshoot is that these proteins can also be altered internally by "tailoring" the gene itself. Thus more specific or more potent agents could be developed, and is regularly being done with chemical changes of drug structure. One subset of genes in the area of cancer are the transforming genes or "oncogenes" of cells. The gene products of the oncogenes are made in rather low amounts and sometimes they are essentially undetectable under normal conditions. This new technology can, for the first time, allow the sizeable production of these oncogene proteins in bacteria. The availability of transforming gene proteins permits the studies of structure and isolated function as well as raising of specific antibodies to inactivate the detrimental effects of these proteins.

Regarding artifically produced antibodies, there are billions of potential producing cells in the body, but each cell produces only a single form of antibody which has a unique site which locks onto the antigen. Under normal circumstances, the innoculation of even a single antigen results in a mixture of antibodies in the serum. After some time, the production of antibody diminishes unless there is a restimulation or a "boost" by added antigen. To get pure antibody to be reactive with a single determinant of an antigen, one must manipulate the system by first isolating a single antibody producing cell, then making it immortal, and finally by expanding it to sizable quantities. The antibodies produced after this procedure will be "monoclonal", that is, have a single specificity. There are several ways which can be used to obtain this result, but the most common is to make a cell hybrid of a normal

antibody-producing cell and fusing it to an immortal cancer cell derived from antibody-producing cells. The resulting "hybridoma" will produce one species of antibody continually without undergoing the eventual cell death as occurs in normal cells. The majority of hybridomas produced today are such that both cells used as partners for the fusion are derived from mice, so that the antibody will be of mouse origin which is rejected by the human species. Therefore, much of the effort is geared toward producing human-mouse and human-human hybridomas which would release human antibodies. However, even with mouse monoclonal antibodies, significant advances are being made in both diagnosis and treatment of cancer patients. The monoclonal antibodies can be prepared against a specific tumor cell protein which is not found on normal cells. Then these antibodies can be "armed" with a toxin or a radioactive metal that can be attached to the antibody. The armed antibody "homes in" onto the tumor cell with exquisite specificity and the toxin or the radiation kills the tumor cell. Other types of radioactive compounds can be attached so that when the armed monoclonal antibody attaches itself to tumor cells, the location of the tumor can be identified in the body.

At this time, tagged mouse monoclonal antibodies are being used to localize various types of human tumors. The killers of tumor cells -- derived from several types of leukemias and lymphomas -- by monoclonal antibodies has been successful in patients so that a number of people are alive today, in complete remission, after conventional means of therapy has been exhausted. There is an enormous amount of activity in this area, because rapid applicability of the research finding to the patient is possible in this system.

DIET AND CANCER

Question: We note last year's National Academy of Sciences Report on diet and cancer which recommended consuming less saturated and unsaturated fat, and eating more fruits. What are you doing with this information -- and how has it changed your research goals?

Answer: National Cancer Institute staff are participating with staff from the National Center for Health Statistics, the Centers for Disease Control, the Food and Drug Administration, and the Office for the Assistant Secretary for Health in the formulation of a plan for a National Nutrition Monitoring System. Such a system would monitor the dietary intake of a statistically valid sample of the population to see whether people are following these recommendations.

NCI staff has developed two research plans - a Diet, Nutrition and Cancer Plan and a Chemoprevention Plan - to stimulate and coordinate research in this area.

As part of the Diet, Nutrition and Cancer Plan, NCI is initiating several clinical trials of diets low in fat and high in fruits, vegetables, and cereal and grains. These trials will address the following issues:

1. Can the results from animal research be applied in humans?

2. What is the pattern of acceptance and participation in this type of diet?

3. Are there any adverse health effects of this diet?

4. What are the costs and benefits?

Under the Chemoprevention Plan, NCI is initiating new studies in animal models, new epidemiological studies, and a spectrum of clinical trials. The clinical trials are evaluating the safety of chemoprevention agents and their ability to reduce cancer incidence.

NCI is supporting behavioral research to evaluate the effectiveness of different strategies for changing eating behavior. Reducing dietary fat will be the emphasis in these studies and the endpoints will include measurements of the amount of fat eaten.

Questions Submitted by Senator William Proxmire

CANCER VACCINE

Question: The discovery of the first virus which may cause cancer in humans is an exciting step; particularly since it could result in the production of a vaccine.

Recently I have received a number of letters that have cited an article by a Dr. Samuel Epstein entitled The Politics of Cancer as well as a series that has appeared in Penthouse Magazine critical of the so-called cancer establishment.

These letters refer to a cancer vaccine and a cancer tracing drug based on a bacteriological connection that will be clinically tested in Canada.

Can you comment on the articles and clinical test cited in these letters?

Answer: In the twelve years since the passage of the National Cancer Act in 1971, scientists have made many advances in the control of cancer. Although they have identified no single drug or therapy that can cure all of the more than 100 forms of the disease, they have certainly reduced the death rate for a number of cancers. Statistics available from the NCI's Surveillance, Epidemiology and End Results (SEER) Program have shown that cancer patients are living longer than ever before. Types of cancer that show marked improvement in five-year relative survival rates for white patients diagnosed between 1973 and 1979 include: endometrial cancer, with a survival rate of 87 percent; female breast cancer, 72 percent; melanoma of the skin, 76 percent; and bladder cancer, 71 percent. For black patients, sites with improved rates include endometrial cancer, 45 percent; breast cancer, 60 percent; bladder cancer, 43 percent; and colon cancer, 44 percent. Fully 47 percent of cancers diagnosed in white patients from 1973 to 1979 are curable. When all races and sexes are combined, the figure is 46 percent. These numbers probably underestimate five-year survival of patients being diagnosed today, due to continued rapid progress in cancer diagnosis and treatment.

Success in treatment is particularly striking in the younger--under 45--age group. Today, children under age 15 with cancer have a 54 percent chance of being cured. Testicular cancer--the leading cancer in men age 25 to 32--has reached a cure rate of 70 percent in advanced cases and almost 95 percent in localized cases through development of new drug therapy. Also, due to the development and skillful use of radiation and drug therapy, up to 70 percent of patients with advanced Hodgkin's Disease are curable.

On the bacteriological connection to cancer, scientists feel that there is no evidence that bacteria can cause cancer. However, studies of viruses have produced interesting clues about the way normal cells become cancerous. While at this time it appears unlikely that a general preventive vaccine for cancer is a realistic possibility, vaccines and other ways to stimulate the immune system as a means of cancer treatment are under study at many research centers. The recent discovery of the first human RNA tumor virus by Dr. Robert Gallo of the NCI intramural program and an uncommon cancer associated with it offers the possibility that cluster vaccinations can be used in endemic areas such as southern Japan. Further epidemiologic work is underway to determine the degree to which the virus spreads horizontally.

Over the past six years, congressional committees or subcommittees have held investigative hearings on NCI programs, in addition to the annual appropriations hearings on the NCI budget. These hearings have served to reassure the public that the money spent on cancer research is well-managed and used to support those areas that show the most promise for further progress.

COMMUNITY CLINICAL ONCOLOGY PROGRAM

Question: On page 36 of your justification you state that the Community Oncology Program will lead to "reduced morbidity and mortality through the transfer of the latest knowledge and technology to the community physician." In describing the Protocol Data Query System you state that it is a "link between community practitioners and the most up-to-date information on developments in cancer research." These two programs sound very similar. Could you differentiate between the two?

Answer: The Community Clinical Oncology Program is specifically intended to involve community physicians in clinical trials through participation in National Cancer Institute-approved research protocols. The program will increase participation in clinical trials, thereby answering research treatment questions more rapidly. Evidence exists that new technology can be transferred effectively by having community physicians participate in clinical research activities. It is expected that the benefits of direct participation in clinical trials can be broadly diffused to other community physicians and their patients in order to reduce cancer morbidity and mortality.

The Protocol Data Query System (PDQ) is an automated data system that will provide up-to-date information to community physicians about state-of-the-art cancer care, current research protocols in use and names of oncologists in a defined area.

MANAGEMENT REPORTS

Question: As you know, language was included in last year's report requesting the Cancer Institute to provide us with periodic management reports. The response on page 24 of your justification indicates that a report is being prepared to submit to the Committee and periodic reports on management initiatives will be made. Has the initial report been submitted? If not, when will it be made available to us?

Answer: The requested management report was submitted to the Subcommittee on April 11, 1983. Additional copies have been provided.

Question: What is your timetable for submitting periodic reports on other management initiatives?

Answer: Our timetable for submitting additional reports to the Committee would be subject to the requirements of the Committee. In the future, specific management reports will be prepared on management initiatives at the request of the Committee.

CORE CENTER REPORT

Question: You indicate on page 26 of your justifications that a report on core grants for Cancer Centers will be submitted to the Committee before hearings on the fiscal year 1984 appropriations. The minority staff has no record of receiving such a report. Has it been submitted?

When will this report be made available?

Answer: A document entitled Report on Trends in Cancer Centers Funding was submitted to the Senate Committee on March 9, 1983. Additional copies have been provided.

CANCER VS. RACE

Question: I found the five year cancer survival statistics on page 36 of your justification both encouraging and discouraging. It was encouraging to note that survival rates are going up. However I was saddened to read that if I was black and got cancer of the bladder my five year survival rate would be 43 percent whereas my survival rate as a white is 71 percent.

Is this discrepancy just a matter of economics, and what are you doing about it?

Answer: Data from the Surveillance, Epidemiology, and End Results (SEER) program indeed indicate a substantial difference in 5-year relative survival rates between white and black patients with bladder cancer. Part of the difference is due to the fact that black patients more frequently have disease that has progressed beyond the localized stage at diagnosis. However, even for patients with localized cancer, white patients still have a substantial survival advantage. Socioeconomic status and life style probably play a role which underlies the above observations but the extent to which these factors explain the

survival differences is not known. It is of interest to note that bladder cancer is the only site for which a black/white survival difference was noted in a study of patients treated by Veterans Administration hospitals where economic status would be expected to be much more uniform than in more general populations covered by the SEER program. This suggests that factors in addition to socioeconomic status must contribute to the black/white survival difference.

A study of patients with cancers of the breast, colon, bladder and uterus is being conducted to investigate further the survival differences that have been observed. Among the factors in addition to socioeconomic indicators to be considered are: delay in seeking medical care, nutritional status, concurrent illness, overall health status, histologic features of the cancer, extent of disease and compliance with planned treatment.

EPIDEMIOLOGICAL RESEARCH

Question: You indicate on page 44 that a portion of your $45,071,000 epidemiology program in the cause and prevention area will be spent on collaborative research with the Radiation Effects Research Foundation in Hiroshima, Japan, to build on the organization's post atomic bomb mortality follow-up. Has there been any attempt to conduct epidemiological research in cooperation with the Defense Department into the mortality and morbidity of U.S. troops exposed to atomic radiation in the course of our post-World War II above ground atomic tests?

Answer: Research on the mortality and morbidity of U.S. troops involved in atomic weapons testing has been conducted by the Centers for Disease Control, which studied leukemia incidence among participants at Shot Smoky in Nevada, and by the Medical Followup Agency of the National Research Council, the research arm of the National Academy of Sciences. The Followup Agency was set up after World War II specifically for the purpose of conducting epidemiologic research on veterans, and it is uniquely qualified to study military participants in nuclear weapons tests.

COMPETING PROJECTS

Question: Dr. DeVita, on page 12 of your justification you showed a drop of 30 percent in the number of new projects to be supported. I assume this has changed in view of your recent budget revision. Can you tell us now whether you will be cuting the number of new project awards and by how much?

Answer: The current budget plan would enable the National Cancer Institute to support some 480 new research project grants in FY 1984, an increase of 15 percent and 62 grants over the projected level in FY 1983. In addition, 337 competing renewal grants will be supported, a decrease of five from the 1983 level.

TRAVEL BUDGET

Question: Dr. DeVita, I note that you are requesting a 13.5 percent increase in the Cancer Institute's travel budget

next year. Why is an increase of this magnitude necessary at a time when the Institute is requesting a total budget increase of only one half of one percent?

Answer: The increase for travel in fiscal year 1984 is necessary in order to take best advantage of some unique opportunities in the field of cancer research, particularly those resulting from the recent strides in biological knowledge. The increase will allow:

- increased travel associated with rapid developments in scientific research, including studies on monoclonal antibodies, and human tumor leukemia virus (HTLV). Travel to the areas where the HTLV appears to cluster will be necessary in order to adequately pursue research on this discovery;
- collaborative studies with Japan to follow up leads concerning radiation effects;
- travel in response to emergent health problems associated with NCI, such as the Acquired Immunodeficiency Syndrome;
- closer monitoring of grants and contracts;
- necessary travel in conjunction with program expansion in the areas of chemoprevention, radiation, community programs, diet and nutrition, smoking and health, and Cancer Control Research Units; and
- initiation and development of community-based programs which will initially require travel by NCI staff to local communities.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

STATEMENT OF DR. CLAUDE LENFANT, DIRECTOR

ACCOMPANIED BY:

DR. JAMES B. WYNGAARDEN, DIRECTOR, NIH
DR. JAY MOSKOWITZ, ASSOCIATE DIRECTOR, SCIENTIFIC PROGRAM OPERATION, NHLBI
NORMAN D. MANSFIELD, DIRECTOR, DIVISION OF FINANCIAL MANAGEMENT, NIH
ANTHONY ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET, DHHS

INTRODUCTION OF ASSOCIATES

Senator WEICKER. Next, we will hear from the National Heart, Lung, and Blood Institute, which has the second biggest budget at NIH.

The April budget for the Institute requests $637.7 million, or $9.7 million above the request made in January, and $14.9 million more than the 1983 level.

The witness is Dr. Claude Lenfant, Director of the Institute.

Welcome, and please proceed with your opening statement.

Dr. LENFANT. Thank you, Mr. Chairman.

Next to me is Dr. Jay Moskowitz who is the Associate Director for Scientific Program Operation of the Institute.

I am pleased to be here and to report on some of the activities of the Institute and to say that we continue to make progress in all our areas of research.

As you know, most of our resources are invested in the acquisition of new knowledge while we also pursue the application of that knowledge to betterment of health and to prevention and treatment of disease.

I would like to give you some examples of the directions that we are going. I would like first to mention a most promising treatment of coronary artery obstruction, which involves injecting into the artery a drug to dissolve the blood clot that is responsible for the obstruction and causes the heart attack.

However, this technique is still under evaluation. In fact, the Institute initiated this year a study to compare the effects of injecting the drug directly into the coronary artery, with injecting it into a peripheral vein. The latter mode would eliminate the need for sophisticated, complex facilities and would make the treatment more available as well as less expensive than when the drug is injected into the coronary artery.

Let me briefly turn to another area of research and mention some work in our high blood pressure program, which is a program of im-

portance to the nearly 60 million people in this country who are considered to have elevated blood pressure.

In addition to the prevention, detection and treatment program that we are conducting jointly with the Department of Health in several States—and one of them is the State of Connecticut—I wish to say we are conducting a very exciting research program, using recent advances in neuro-biology and in genetics.

For example, we have recently reported a new test which may enable us to identify individuals susceptible to development of high blood pressure before an increase actually occurs.

I would like to conclude my remarks here because of the time limitation, but wish also to emphasize that I have mentioned work in only 2 of the 22 programs of our Institute, which include blood and lung as well as heart disease.

I would be pleased to answer any questions.

COMPETING RESEARCH GRANTS

Senator WEICKER. Thank you very much.

Let's just start off on the same line of questioning that I directed toward Dr. DeVita first as to the general question on the competing grants—given your choice whether or not you would like to have a greater number at lesser dollars or fewer number at greater dollars.

Dr. LENFANT. Well, I think I will come down pretty much like Dr. DeVita and say that it would depend on the type of research that we are talking about.

The fact is, Mr. Chairman, that we feel we are surrounded by opportunities. Dr. DeVita was mentioning the new molecular biology which has evolved during the last few years. We are now ready to capitalize on that biology as well as on genetics, cell biology and immunology, so we feel a need to support these programs and to support them as fully as possible.

But to answer your question, whatever choice we make will necessitate a trade off.

Senator WEICKER. And the second part of my question related to the cut which would take place in terms of these other activities to achieve the additional moneys for the 5,000. Does that also impact upon the totality of those matters that you are working on?

Dr. LENFANT. Indeed, it will. I am referring to centers which we will now be unable to support in our Institute. We would also curtail other programs. But again, I want to emphasize our very strong commitment to the research grants program of the Institute because we think that it puts us on the frontier of new research and new advances which, as Dr. Wyngaarden was mentioning, 10 years from now will be paying off.

Senator WEICKER. Or investments that are not made now will not be paying off.

Dr. LENFANT. Well, that is correct, yes.

PRIORITIES FOR ADDITIONAL FUNDS

Senator WEICKER. Let's make the assumption—I haven't counted the votes so maybe it is a very weak assumption, but let's make the assumption—that the committee does vote extra funding. Do you suggest that the funding be directed toward raising the level applied toward the competing grants or that we take action on the line item as it applies to the research centers, which would be your choice—as I say, this is a hypothetical question which I pose. I just would appreciate getting some direction as to what the committee's action might be.

I fully understand you recommend the administration point of view, but I also would like to know if the additional money is appropriated on top of what the administration has requested, should we put it in the competing grants or the areas being cut to provide the money that is being shifted over?

Dr. LENFANT. I think it would depend on the Institute. I am sure Dr. Wyngaarden would want to speak on behalf of NIH as a whole.

From the viewpoint of our Institute, we feel that the achievements that we have made during the last 10 years can be attributed to our balanced programs. I am sure you heard about the decrease in the death rate of coronary heart disease. In fact, I would like to take this opportunity to mention that last year was the first year since 1948 that less than one-half of the deaths were due to heart diseases.

Before that more than one-half of the deaths in this country were always due to cardiovascular disease. Last year was the first time since 1948 that it was less. And the reason why we have achieved that decrease is because our program has been balanced between basic research, applied research, and translation and education.

Our feeling is that we will have to maintain such a balance to continue the successes we have had until now.

Dr. WYNGAARDEN. Perhaps I could emphasize, Mr. Chairman, that we don't view this as a severe downward negotiation of new projects. We have made a policy decision to fund such projects as we can support adequately for the execution of that work.

The downward negotiation this year would average about 10 percent. That compares with negotiations that have ranged from 3 to 15 percent during the past 10 or 15 years.

We have made that policy decision to support the research project grants adequately. It is a little below last year's level, but it does represent some increase. And that, I think, is an answer to your hypothetical question.

Senator WEICKER. Now, as far as the Heart, Lung, and Blood Institute, I gather, according again to the NIH memorandum, the centers that would be eliminated would be Adult Respiratory Failure Centers, University of Texas, University of California at San Diego, Massachusetts General Hospital, is that right?

Dr. LENFANT. That's correct, yes, sir.

ARTIFICIAL HEART RESEARCH

Senator WEICKER. While I have the opportunity, I am sure that I and others in this room would like to hear your evaluation of the situation as it related to Dr. Clarke. Would you characterize this clinical experience a success or a failure or what is your evaluation of it?

Is it an area that your Institute itself has been involved with?

Dr. LENFANT. Well, our Institute, Mr. Chairman, has been very much involved with the research which has led to what we have witnessed during the last few months. In fact, our Institute has been at the forefront of the circulatory assist program of which the artificial heart is one of the components.

We have, over the years, committed a number of our moneys to this program. And I should say that today, our commitment is less than it was 10 or 15 years ago because of competing needs and all of the things that we have to do.

With regard to the clinical application of the artificial heart to Dr. Clarke, our Institute was not involved with that. Again, our participation in the whole thing has been in the development phase; the construction of the device. But the clinical application was not supported by us.

Now, the other question is a more difficult one to answer. We feel that it was not a wasted effort. We think that if we are to support a comprehensive program in cardiovascular diseases, we have to include such devices.

Whether this particular case was a success or a failure on the basis of the outcome itself, I would say, it did not succeed for very long. But on the basis of what has been learned from that experience, I would say it was a success.

But I would like to conclude my answer which is long-winded——

Senator WEICKER. No; it is very interesting.

Dr. LENFANT [continuing]. By saying that this is not the bottom line or the end of the road. Our effort and our commitment is to research toward the prevention of heart diseases, so that we don't have to resolve such extreme conditions.

MULTIPLE RISK FACTOR INTERVENTION TRIAL

Senator WEICKER. We understand that one outcome of your 10-year, $115 million study of the causes of heart disease indicated that changing life style rather than using certain prescription drugs may be the more effective way to deal with hypertension.

Can you tell us about this?

Dr. LENFANT. I assume the study that is being made reference to here is the multiple risk factor intervention trial, or MRFIT, which is indeed a study that the Institute has supported for about 10 years at a fairly high cost, as you just mentioned.

Basically, the purpose of the study, Mr. Chairman, was to intervene on risk factors which are attributed to the development of coronary heart disease. We looked at high blood pressure, smoking, and eating habits.

We have been very successful—in fact, beyond our expectation—concerning these factors and in leading to the reduction of these factors in the groups on which we intervened.

I should say that we also have learned, as an outcome of that study, that in fact during the last 10 years the American people by themselves, without special intervention, have begun to understand that some habits must be modified. I am saying this because the critics of the MRFIT study are saying, "But the control group did very well, too." This is good, and we view that as a success in many ways because it shows that all that has been done during the sixties to educate the American public about risk factors has paid off. But with the practices that constitute our special intervention, they would have done even better.

Now, with regard to hypertension, which is what you were asking about, there is no doubt that through these programs, and other programs, we have been able to identify individuals with high blood pressure. We have mounted a national education program about high blood pressure control. We think that this program can be viewed as the cause of some of the reduction in heart disease that was mentioned earlier.

And certainly the reduction in death rate due to strokes, which has been about 42 percent during the last 10 years can be attributed to the impact of our high blood pressure education program. I mentioned in my opening remarks, that high blood pressure is a very serious problem in this country. We consider that 60 million Americans have elevated blood pressure. We have to do something for these people in addition to our education and prevention program. As I said, we have a very energetic basic research program that we are conducting about the problem.

Senator WEICKER. Let me say this: Any valid study of hypertension as it relates to life style, I think should include the U.S. Senators like myself looking over a Reagan science budget.

Dr. LENFANT. Well, I would be most happy to talk to you about it directly.

PREPARED STATEMENT AND SUBMITTED QUESTIONS

Senator WEICKER. Thank you very much, Doctor. We will insert your prepared statement in the record.

There will be other questions for the record.

[The information follows:]

Statement of Dr. Claude Lenfant

I welcome the opportunity to again appear before your committee, this time in my new capacity as director of the National Heart, Lung, and Blood Institute. I feel especially fortunate to be returning to the Institute at a time when its advisory committees have just completed a 10-year evaluative report that not only places the Institute's scientific achievements in perspective, but also provides a blueprint that we will draw upon in planning our programs for the years ahead. The Institute's past successes, as reported to you by its former directors, have been built on multiple research approaches that we will continue to use in pursuing our objectives. The acquisition of knowledge has been achieved through fundamental, applied, clinical, and population-based research. Knowledge so acquired has then been validated through controlled trials to assess its value in clinical situations. After adequate validation, the transfer of knowledge to community settings and general medical practice has been achieved through demonstration and education programs for both professionals and the public.

The Institute's contributions to the diagnosis, treatment and prevention of diseases within its purview--documented in the 10-year evaluative report--are ample testimony to the importance of sustained interaction in our efforts to acquire, validate and transfer new knowledge. We have in the past capitalized on information gained through studies of traditional disciplines such as biochemistry, physiology, pathology, nutrition, and through clinical and epidemiologic research. Today we have other opportunities because new frontiers have opened through recent innovative approaches in cell biology, immunology, molecular biology, and biochemical genetics. It is a challenge that we welcome as we endeavor to bring this new science to bear on studies of the diseases within our mandate. Some recent studies, highlighted below, illustrate the interplay between basic and clinical research. They show how knowledge gained through fundamental research has elucidated disease processes, and how clinical trials have had an impact on diagnosis and treatment of diseases.

Acquisition of Knowledge

A series of studies, some still in progress, exemplify how the special features of an inherited disease (familial hypercholesterolemia) have contributed to our understanding of the basic processes that regulate blood cholesterol levels, and how such insights have suggested a new therapeutic approach. Atherosclerosis results from cholesterol accumulation in arterial walls, and understanding how its levels are regulated has important implications for the prevention of coronary heart disease. The major vehicle for transporting cholesterol in blood is the low density lipoprotein (LDL). They are processed by specific LDL receptors on cell surfaces that not only remove them from blood but release the cholesterol that then becomes available for normal metabolic functions within the cell. The production of LDL receptors is regulated by the cholesterol content of the cell, the number of receptors increasing as cholesterol content decreases. It is, therefore, of great interest that a genetic defect in familial hypercholesterolemia leads to an absence of normal numbers of LDL receptors. This observation suggested the possibility that using a new drug, an Acetyl CoA reductase inhibitor, that specifically inhibits cholesterol synthesis, might correct the

abnormality in number of LDL receptors in familial hypercholesterolemia. Animal and early clinical studies of this drug have been successful enough to indicate that it might become a powerful tool for treating familial hypercholesterolemia and provide a better understanding of the role of metabolic processes in health and disease.

Another recent study illustrates how studies of molecular biology and gene expression have resulted not only in new knowledge but in a clinical application. A drug used to modify the expression of a gene has the potential of correcting a hemoglobin abnormality that characterizes sickle cell anemia and thalassemia (Cooley's anemia). Preliminary results indicate that this drug corrected some of the physiologic abnormalities in thalassemia patients. In both of these blood disorders hemoglobin in the fetus is normal, but the hemoglobin that enters the bloodstream after birth either lacks specific subunits essential for normal function, or contains abnormal subunits. In a study designed to replace the abnormal globin subunits with those found in fetal hemoglobin, investigators used 5 Azacytadine (a drug used in cancer therapy) to "turn on" the genes for production of fetal hemoglobin. In animal studies, and subsequently in a few patients, the hemoglobin had subunits typical of normal fetal hemoglobin and patients experienced considerable physiologic improvement. This very promising development is being pursued to determine whether such a regimen is effective and safe enough for wider clinical use.

The development of large quantities and diverse types of monoclonal antibodies has been widely utilized in research on cancer and infectious diseases, but some recent studies are making innovative applications of the technique to studies of cardiovascular diseases. Digoxin, a pharmacological agent widely used to improve function in a diseased heart, has toxic side effect that are not uncommon if the agent is used in excess. Antibodies to digoxin have recently been developed as a therapeutic agent and used to reverse rapidly the dysrhythmias resulting from digoxin toxicity.

In another approach, mono- and polyclonal antimyosin antibody labelled with Technetium-99m has been used to visualize the size of acute myocardial infarcts by gamma camera. The success of the technique depends on the fact that increased permeability of the cardiac cell membrane resulting from myocardial infarction allows penetration and concentration of the antimyosin antibody in the cardiac cell. This may have potential as a diagnostic technique.

Fundamental insights into the roles of specific prostaglandins are of clinical interest relative to the diffuse lung injury adult respiratory distress syndrome that results from such diverse causes as trauma, sepsis, pneumonias and endotoxic shock. This catastrophic condition is only minimally responsive to therapy and has a mortality approaching 90 percent. There is, however, hope that ARDS may be prevented by interrupting the common pathways by which different initiating events cause similar diffuse lung damage. Two prostaglandins of interest are prostacyclin and thromboxane, which are normally in balance. Thromboxane increases in a number of lung injury syndromes and its potency as a vasoconstrictor accounts for the pulmonary hypertension associated with these conditions. Prostacyclin, a potent vasodilator, not only decreases thromboxane production but has been shown to have a beneficial effect when infused in patients with pulmonary hypertension.

Validation and Transfer of Knowledge

Clinical trials are the most reliable approach to validate knowledge acquired through research and to determine whether it is ready for wider application in community settings. Such trials are characteristically long-term and usually expensive enterprises because they include a planning phase, a long period of patient recruitment and data collection, and an additional period for analysis and interpretation of the data.

Most recently completed and a subject of widespread interest was the NHLBI multiple risk factor intervention trial (MRFIT) that began 10 years ago and was reported in September 1982. The trial involved 6,500 middle-age males selected because they were at high risk for heart disease and would participate in an intervention program to reduce cigarette smoking, high blood pressure and high levels of cholesterol. An unanticipated aspect of the study was that changes evidently occurred in the U.S. population, which appears to a large extent to be heeding advice about the importance of controlling risk factors. This is suggested by an unexpected finding in the trial; namely that the over all decline in frequency of heart attacks in the experimental group was not significantly different from the decline in a comparison group that was similar in all respects except that instead of an intervention program planned and executed as part of the trial they received "usual care" by their physicians. Although the study has terminated, data analysis is continuing and new findings will be reported as they emerge.

Among findings that will be awaited with interest are further analyses of data on patients with moderate hypertension and cardiac abnormalities. The MRFIT study revealed an unexpected increase in mortality among patients who had electrocardiographic abnormalities and were receiving diuretics for diastolic pressures in the range of 90 to 94 mm Hg. There is, in fact, considerable controversy about the treatment of certain types of patients. Although dramatic benefits have accrued from methodical treatment of hypertension and from the NHLBI outreach programs to inform community physicians and the public about the importance of medication, there remain questions that can only be resolved through further research.

Another clinical trial the "systolic hypertension in the elderly program" (SHEP) is being jointly supported by the National Institute of Aging and NHLBI to determine the benefit of treatment of elderly persons with systolic hypertension but diastolic pressures that are below 90 mm. An investigator-initiated pilot study involving five institutions and a coordinating center is now in the third year (followup phase) of a four-year trial to identify the critical elements to be included in a full-scale trial. The study involved 500 patients in the pilot phase, but is estimated to require about 4,500 for the full-scale study which is to be undertaken if warranted after assessment of the pilot study.

An investigator-initiated clinical trial is assessing the effect on cardiovascular mortality of alternate-day consumption of aspirin, and at the same time, to examine the effect on cancer incidence of alternate-day consumption of beta carotene. An estimated 22,000 male physicians between ages 50 and 75 are being recruited in the study. Jointly supported by the National Cancer Institute

and NHLBI, the trial will determine cardiovascular mortality, total mortality and coronary events as endpoints.

The transfer of validated knowledge to the public and for use in professional practice is achieved through demonstration and control programs. Antismoking information has been of great importance, because smoking cigarettes has now been identified as the predominant risk factor for lung disease. Results from epidemiological studies are, however, now showing that other factors, including genetic predisposition, environmental and industrial pollutants, age, race, and familial factors, may also be involved. Large population studies have also demonstrated an association between chronic obstructive lung disease and such factors as occupational exposure, social environment, and a history of childhood respiratory disease.

As awareness of the diversity of the deleterious effects of cigarette smoking is growing, increased interest is turning towards the effects on the nonsmoker of breathing air polluted with cigarette smoke, so-called "passive" smoking. A study has recently been completed which shows that children from homes with smoking parents have a higher incidence of respiratory symptoms and hospital admissions than children with nonsmoking parents. This is important because children who experience respiratory damage early in life are at increased risk of developing lung disease as adults.

A new health problem with dimensions not yet fully realized is a dysfunction of the immune system called acquired immune deficiency syndrome (AIDS) Characterized by high mortality and a baffling clustering of cases among male homosexuals, recent Haitian refugees, intravenous drug abusers and some patients with hemophilia, AIDS is of great interest to NHLBI because it is suspected that it might be transmitted via blood transfusions. In a study jointly supported by the Centers for Disease Control and NHLBI, patients receiving multiple blood product transfusions are examined to determine whether they develop T-cell abnormalities that lead to the more severe AIDS.

As reported by my predecessors over the years, there are abundant tangible evidences of the success of NHLBI programs, the most eloquent being an over all 25 percent decline in mortality from coronary heart disease that has occurred in both men and women durduring the last decade. Even more noteworthy is the 35 percent decline in the age group 35 to 45, which means fewer men and women succumbing to heart disease during their most productive working years. But it is premature for the NHLBI to be pleased about its successes while the situation relative to lung diseases continues to cause dismay. During the same period that deaths from cardiovascular diseases have declined, deaths from chronic obstructive pulmonary diseases (COPD) have increased more than 26 percent. We are indeed faced with a dual challenge because we must not only find ways to reduce mortality from lung diseases but must also seek ways to further diminish cardiovascular mortality, which has now virtually plateaued at about 50 percent of all deaths. The tragedy of blood diseases continues to be evident in that they often kill early in life and are in fact responsible for many cardiovascular and pulmonary disorders. The tools for success are at hand. New technologies and new basic science approaches are available and ever increasing. We must now turn our attention increasingly to

innovative ways to tap these rich resources, with the ultimate goal of disease prevention through improved understanding of the mechanisms that underlie their development.

Mr. Chairman, I have presented only a few of the Institute's accomplishments and future prospects. The 1984 budget request for the National Heart, Lung, and Blood Institute is $637,738,000. I will be pleased to answer any questions the committee may have.

Biography of Dr. Claude Lenfant

LENFANT, DR. CLAUDE
Director, National Heart, Lung,
and Blood Institute, NIH

October 12, 1928, Paris, France

Education. B.S., University of Rennes, France, 1948. M.D., University of Paris, France, 1956.

Professional History. 1957-1958, Research Fellow, University of Buffalo, New York. 1958-1959, Research Fellow, Columbia University, New York. 1959-1960, Assistant Professor of Physiology, University of Lille, France. 1961-1965, Clinical Instructor of Medicine and of Physiology and Biophysics, University of Washington, Seattle. 1966-1967, Clinical Assistant Professor of Medicine and of Physiology and Biophysics, University of Washington, Seattle. 1968-1971, Associate Professor of Medicine and of Physiology and Biophysics, University of Washington, Seattle. 1970-1972, Acting Associate Director, Collaborative R & D Program, National Heart and Lung Institute, NIH. 1970-1972, Associate Director for Lung Programs, National Heart and Lung Institute, NIH. 1971-1972, Professor of Medicine and Physiology and Biophysics, University of Washington, Seattle. 1972-1980, Director, Division of Lung Diseases, National Heart, Lung, and Blood Institute, NIH. 1981-1982, Associate Director for International Research, NIH. 1981-1982, Director, Fogarty International Center for Advance Study in the Health Sciences, NIH. 1982-Present, Director, National Heart, Lung, and Blood Institute, NIH.

Professional Organizations. Association of American Physicians. American Society for Clinical Investigation. American Physiological Society. American Society for Clinical Research. French Physiological Society. International Federation for Medical Electronics. American Society of Zoologists. Society for Experimental Medicine and Biology. Undersea Medical Society. New York Academy of Sciences. Served on Editorial Boards of eight Scientific Journals.

Honors, Awards and Publications. Thesis Prize, University of Paris, France, 1956. Commendation, Tohoku Medical Society, Sendai, Japan, 1973. Superior Service Honor Award, DHEW, 1974. University of California, Los Angeles, Regents' Professor, 1978. Testimonial Dinner, American Thoracic Society, 1979. Honorary Fellow, American College of Chest Physicians, 1979. Honorary Professor, National Yang-Ming Medical College, Taipei, Taiwan, 1980. Honorary Professor, Universidad Peruana Cayetano Heredia, Lima, Peru, 1981. Author or Coauthor of 175 scientific publications. Executive Editor of a 24 volume series of monographs on "Lung Biology in Health and Disease."

Questions Submitted by the Subcommittee

NEW BUDGET FOR '84

Question: How many additional new and competing grants will you get above the January budget -- and what further research will you be able to do as a result?

Answer: The original President's Budget provided funds for 566 competing research project grants. The revised President's Budget provides funds for 729 competing research grants, an increase of 163.

This higher number will permit additional awards for the acquisition of new knowledge toward understanding of the etiology, pathogenesis, treatment and prevention of cardiovascular, pulmonary, and blood diseases. Additional research will be pursued in such promising areas as the neurobiology of hypertension; use of monoclonal antibodies in the study of cardiovascular diseases; the role of exercise in therapy for chronic obstructive pulmonary disease; biochemical and cellular alterations in lung tissue associated with cystic fibrosis; development of drugs to treat sickle cell anemia; and studies on methods of reducing the buildup of iron in Cooley's anemia patients.

AVERAGE COST OF GRANTS

Question: It is our understanding that the January and April Budgets both assume cuts in the average award for new and competing grants below what the full average cost would be. For new grants this appears to be a difference of some $17,800 ($142,400 full cost vs. $124,600 in revised budget). How will this affect your Institute -- and to what extent will it start changing the scope and quality of the projects that are reviewed by your study section?

Answer: Although we will not fund new awards at full costs, funds are provided to allow a slight increase over the average FY 1983 costs. The average cost for new and competing grants favorably recommended by our Advisory Council is projected by the computerized model to be $158,432. Under our revised budget, however, the amount awarded will be $146,052. The difference, therefore, is $12,380, an average reduction of approximately 8% for these competing awards.

A further reduction could require slower research progress or deferral of parts of the proposed study.

Question: Under your budget revision, the average NIH noncompeting grant award is projected to decrease by about $12,400 below what the full average cost would be ($143,100 full cost vs. $130,700 in budget revision). How will it change the scope and quality of the projects that are reviewed by your study section?

Answer: The FY 1984 request proposes an 8% increase over the average cost for noncompeting grants awarded in FY 1983. In 1984 the average noncompeting grant is projected to be $168,466 full cost. The average award, under the revised budget proposal, will be $155,034. The difference is $13,432, a reduction of 8% from the study section recommendation, although still higher than FY 1983.

The reduction in funds will, therefore, have some impact on the quantity and pace, but not the quality, of research being accomplished.

SPECIALIZED CENTERS OF RESEARCH

Question: The Administration proposes to make cuts from the January budget in grants to specialized and comprehensive research centers. How does this affect your program - and what will it do to research at those centers?

Answer: The revised 1984 President's Budget permits the funding of 54 research centers compared to 57 centers in FY 1983. Three competing renewal adult respiratory failure centers would not be funded. In addition, continuing centers would be reduced by an average of approximately 11 percent. Since the budgets of the Institute's specialized centers of research (SCORs) are close reflections of the actual cost of doing research, negotiated reductions will result in declines in research effort and productivity proportional to the size of the budget cut and consequently slow down progress.

Moreover, the Adult Respiratory Failure SCOR is currently under review and cannot continue under the 1984 budget policy. A decision not to fund any new programs would, in effect, completely eliminate this program. Epidemiologic studies establishing risk factors and predictors of respiratory failure represents an area of research that is supported only through these centers.

CLINICAL TRIALS

Question: To what extent will any clinical trials be affected by the proposed cuts in research and development contracts and cooperative clinical research?

Answer: The research and development contracts budget for the National Heart, Lung, and Blood Institute (NHLBI) is the same in the original 1984 President's Budget as it is in the revised version. Contracts for cooperative clinical research are also the same in both budgets. The funds requested for these NHLBI programs will permit the clinical trials begun in FY83 to continue. These trials include: Thrombolysis in Myocardial Infarction, Cardiac Antiarrhythmic Agents, Systolic Hypertension in the Elderly, and Diagnosis of Pulmonary Embolism. This budget also permits the continuation of ongoing clinical trials and analyses of data for those trials that have completed the data collection phase.

RESEARCH TRAINING

Question: The new budget proposes to eliminate the 5% stipend increase for predoctoral and postdoctoral training, to make further reductions from the January budget in the number of trainees, and to decrease the number of research career awards to promising scientists. What effect will these steps have on your Institute's training program--and what effect will it have on your people contemplating careers in biomedical research?

Answer: It is correct that the current plan proposes elimination of the 5% stipend increase in 1984; however, the number

of trainees is not reduced from the January budget. I should point out that a 5% stipend increase was authorized in 1983, which provided encouragement to the trainees. Young people contemplating careers in biomedical research are concerned with continuing support, growth, and advancement. Stabilization of grant support, by funding 5,000 new research project grants each year, should help to answer that concern.

An important group of research career program awards includes the Clinical Investigator Award (CIA) and the Special Research Career Award - Diabetes Mellitus, which are designed to encourage newly trained clinicians to develop clinical and research interests and skills and to increase the pool of physician investigators in biomedical research. These are new programs which were launched to reverse the decline in the number of clinical investigators. Additional programs are planned to encourage clinicians to undertake careers in fundamental biomedical sciences such as molecular biology, genetics, and biophysical chemistry.

Our national needs are growing, not just in numbers but in different kinds of investigators needed as a result of the advances in research supported by the NHLBI. An example is the emerging medical discipline of transfusion medicine which is concerned with the proper use or removal of blood, its components, derivatives, and substitutes in the treatment or prevention of disease states. Our continued support of the research career program helps us to meet these recently recognized needs.

RESEARCH RESOURCES

Question: To what extent will the proposals to reduce funding for General Clinical Research Centers and Biomedical Research Support Grants affect biomedical research in general and your Institute's work in particular?

Answer: The proposals to reduce funding for the General Clinical Research Center (GCRC) and the Biomedical Research Support (BRS) grants were two reductions necessitated by the decision to fund 5,000 new and competing renewal research project grants within the same total dollar level as in the January budget. GCRCs provide an environment where research studies on patients with genetic and other diseases can be carried out, where the effect of clinical regimens in patients with defined medical problems can be investigated, and where metabolic processes in normal human subjects can be be studied. These centers provide an environment for clinical research characterized by specialized clinical core facilities and equipment shared by numerous investigators, thereby significantly reducing duplication and responding to the need for cost containment.

Research supported through the general clinical research centers often provides the basis on which a major clinical investigation on heart, lung, or blood diseases is initiated. Clinical research is an important part of the National Heart, Lung, and Blood Institute (NHLBI) mandate and a major step in transferring research findings from the basic laboratory to impact on the health care of the public. Many of the major clinical studies now supported through the NHLBI had their initial costs, or pilot studies, supported through the general clinical research centers. A number of hematologic problems are currently being studied in

the Clinical Research Center setting; these include sickle cell disease, Cooley's anemia and hemophilia. These centers provide support for research-related patient care which is therefore not charged directly to the research grants. These centers also provide opportunities for carrying out clinical research in emerging areas, such as in the acquired immune deficiency syndome (AIDS).

The Biomedical Research Support Grants (BRSGs) are an important source of funds for initial studies and for feasibility studies in new and emerging areas. Such studies form the basis for many new grant applications received by the Institute. BRSG funds may also be used to maintain common resources, such as cell lines or special animal colonies, which cannot usually be supported through a single research grant. The BRSGs frequently support young investigators who are initiating their research programs and are in the process of applying for more traditional research support.

NHLBI grantees will have to provide for the loss of funds in these two areas from their own research project grant budget or seek assistance from their institution or other sources.

PROTECTING THE INVESTMENT

Question: At a time when many budgets are going down, Congress has been increasing funding of the National Institutes of Health, including your Institute. We are concerned that these scarce resources be carefully and effectively used and that there be no basis for criticism of your management of this money. What assurances can you give us that your Institute is making careful and effective use of the appropriations we provide you?

Answer: The National Heart, Lung, and Blood Institute (NHLBI) takes its responsibilities for the proper stewardship of federal funds very seriously. NHLBI must adhere of course, to strict legal requirements, but has responsibility also for the wise and effective use of funds entrusted to it. One of the primary methods of accomplishing this task is to enhance competition for the research dollars we award, and to insure that we conduct thorough and equitable reviews of grant applications and contract proposals submitted to us. The National Institutes of Health peer review system is very helpful in this regard. Another method for building effective programs is the NHLBI impementation planning process. This process receives input from both Advisory committees and members of the biomedical community which helps assure that we are addressing the areas of greatest scientific needs and opportunity with the resources we have available.

Question: Outside from the peer review system, what institutional arrangements do you have that serve to deter waste, fraud and abuse in the handling of federal funds?

Answer: The National Heart, Lung, and Blood Institute deters waste, fraud and abuse through policies, procedures and organizational arrangements that carry out existing laws and current regulations, and apply principles of good management. NHLBI takes advantage of the services of the National Institute of Health's alert system and calls on the inspector general's office, and other investigative and audit groups when waste, fraud and abuse are suspected. Our professional staff members adhere to conflict of

interest regulations, review progress reports on grants and contracts, conduct periodic visits at the research site, stay alert for reports of research findings that cannot be replicated and take effective steps when a problem is discovered. The NHLBI staff realize the importance of the creditability of its research programs and work to assure that creditability is maintained.

ARTIFICIAL HEART

Question: We were all so saddended by the death, after a courageous fight, of Dr. Barney Clark, the first recipient of an artificial heart. We note that at least $8 million of your Institute's money went into artificial heart research over the last decade. No doubt you have closely followed the events at the Utah Medical Center in Utah. How would you characterize this clinical experience--a success or failure?

Answer: As a clinical experiment it was a success in that the patient's life was extended beyond what had been anticipated and the device functioned well. It also made important contributions to our understanding of problems that could not have been anticipated on the basis of animal studies alone. From a scientific viewpoint, important new research information was obtained concerning patient safety and physiologic effectiveness. This experience demonstrated that a patient with an artificial heart can be managed using conventional procedures since no new technology, other then the artificial heart, was needed.

Question: Would you prescribe future experiements with this artificial heart--or should medicine look to other methods of treatment, such as heart transplants?

Answer: Limited clinical investigational use should continue to resolve research questions involving implantability of the devices. Both physiologic and morphologic questions may be answered. Complementary forms of therapy, including cardiac transplantation, are needed since different therapies are applicable to different subsets of patients. Cardiac transplantation is currently performed only in patients under 50 years of age and is limited by available donor hearts.

Question: In discussing whether to undertake heart bypass surgery, one point of discussion is whether it will improve the quality of life of the patient. To what extent does this point apply to use of the artificial heart where we saw Doctor Clark suffer terribly as he went through the experience?

Answer: In the case of Dr. Barney Clark, thorough evaluation of his quality of life was not possible because of complications of the parent disease. Greater experience with cardiac transplantation suggest that good quality of life is feasible for those with transplanted hearts. The expectation is that artificial heart recipients will be able to function similarly to those with transplanted hearts, but actual demonstration that good quality of life can result must await further experience.

TREATING HIGH BLOOD PRESSURE

Question: We understand that one outcome of your 10-year, $115 million study of the causes of heart disease indicated that changing life style rather than using certain prescription drugs may be the more effective way to deal with hypertension. What can you tell us about this?

Answer: The study to which you are referring is the Multiple Risk Factor Intervention Trial (MRFIT), which was designed to test the effects of special intervention to lower serum cholesterol, reduce blood pressure and eliminate cigarette smoking, which are three of the major risk factors for coronary heart disease. The special intervention group did reduce its risk factors and the number of deaths for this group were below what would have occurred if no intervention took place. This study showed that the control group did very well also, which means that the American public has reduced its risk factors on its own. We think this information is important and relates in part to public education efforts about risk factors during the 1960s and early 1970s.

Question: What follow-up studies and public information programs are planned as a result of the overall study of the causes of heart disease?

Answer: The research findings from clinical trials of prevention and treatment such as the Hypertension Detection and Follow-up Program, Multiple Risk Factor Intervention Trial, and Beta-Blocker Heart Attack Trial have been widely disseminated to the medical profession and to the public as soon as new information or conclusions from analysis of findings have been available. The research investigators have worked actively with outside expert panels and with the Institute's Office of Prevention Education and Control to see that important findings are rapidly made available. For example, the MRFIT findings have been presented at the national scientific meetings of the American Heart Association in November 1982, the American College of Cardiology in March 1983, and in the High Blood Pressure National Conference in April 1983. Such reporting will continue as additional findings come from all major research areas.

Question: What can you tell us about the new class of drugs which work to inhibit coronary events by blocking certain chemical receptors in the heart blood vessels (calcium blockers, beta-blockers, etc.)?

Answer: Calcium channel blockers are a new class of drugs whose major application at the current time is in the management of variant angina. Additionally, some of these drugs prevent arrhythmias and still others have been found useful in the treatment of peripheral circulatory conditions such as Raynaud's syndrome. These drugs, because of their ability to cause relaxation of vascular smooth muscle, also lower blood pressure. There are several anecdotal reports within the scientific literature espousing the blood pressure lowering effects of these medications. Indeed, when a patient has variant angina and hypertension these drugs can be of unusual benefit because they have dual effects. Although calcium channel blockers, per se, are not at the moment considered a usual step in the management of patients with

hypertension, it would not at all be surprising if in the near future they became a standard component of antihypertensive drug regimens.

Beta blockers, although initially used in the treatment of cardiac conditions, have for many years been standard therapy in the management of patients with hypertension. Many centers in Europe use beta blockers as their first line drug in the treatment of patients with hypertension and increasingly, clinicians in the U.S. are using beta blockers, if not as the first line drugs of choice, certainly the second line drugs of choice in the management of patients with hypertension.

Angiotensin converting enzyme inhibitors are a new family of drugs the primary indication for which has been the management of patients with high renin forms of hypertension. The drugs perform rather well in this condition and represent a step forward in the treatment of hypertension. Unlike other drugs which have either global or non-specific blood pressure lowering effects, this class of drugs exerts very specific effects against very specific forms of hypertension. They have also been found to be beneficial in patients with hypertension due to a connective tissue disease (scleroderma) and also in patients who are suffering from congestive heart failure.

Question: What dietary measures, including limiting salt intake, do you recommend? Should food packages be required to carry labeling for sodium content?

Answer: Although the prevalence of hypertension in the adult U.S. population has been estimated to be between 23 million and 60 million cases, and although some of these patients have a form of hypertension which is exacerbated by salt, there is nevertheless, insufficient evidence at the present time to justify a national policy that would seek to drastically reduce the salt intake of the entire U.S. population, over 75% of whom do not have hypertension. While certain hypertensive patients would benefit from such a policy, we do not have sufficient information to know how such a policy would affect everyone else. Hypertensives as a group tend to benefit from salt reduction. It would appear that the most prudent policy to adopt at this time is to reaffirm the importance of detecting, treating, and following up cases of hypertension and to advise patients to continue to follow the advice of their physicians, including dietary advice. The Institute, however, strongly supports the principle of voluntary sodium labeling in order to permit hypertensive patients and other individuals to make informed choices about the amount of sodium they consume.

MILD HYPERTENSION

Question: Since the Framingham, Massachusetts Study of coronary heart disease, there has been special interest in the problem of mild hypertension and how to deal with it. What is your position on the appropriate course of therapy for individuals with mild hypertension? Do you recommend the use of therapeutic drugs, lifestyle changes, or some combination of both?

Answer: The Framingham Study and other population studies have provided considerable knowledge of the relationship of

hypertension to the risk of coronary heart disease, stroke, and congestive heart failure. The importance of even mild elevations of blood pressure in conjunction with other risk factors, such as cigarette smoking, high cholesterol, and diabetes warrant an evaluation and plan of management of individuals with even mild hypertension.

Findings of the Hypertension Detection and Follow-up Program (HDFP) and the Multiple Risk Factor Intervention Trial (MRFIT) have focused attention on the treatment (especially pharmacologic treatment) of hypertension, especially in the subgroup of patients with so-called mild hypertension.

In considering treatment of mild hypertension, the HDFP demonstrated a significant 20.3% reduction in all cause mortality for the Stepped Care (SC) participants (the aggressively treated group) compared with Referred Care (RC) participants (the comparison group). This HDFP population had a baseline diastolic blood pressure in the range 90-104 mm hg at their first clinical screening. All who were invited to attend this clinic screening had had a diastolic pressure 95 mm Hg or greater at a home or worksite screening. In a further subgrouping of the mild hypertensives, for those who at baseline were not under pharmacologic treatment for their blood pressure and had no evidence of end organ damage, the reduction in mortality for SC vs. RC was 28.6% overall and 34.0% in the group which had blood pressure in the range of 90-94 mm Hg.

The Multiple Risk Factor Intervention Trial (MRFIT), as mentioned previously, did not find any difference in coronary heart disease (CHD) mortality or total mortality between the Special Intervention (SI) group whose blood pressure was treated aggressively in comparison with the Usual Care (UC) group who had less aggressive antihypertensive drug therapy.

To help the National Heart, Lung, and Blood Institute interpret the data from HDFP and MRFIT in context with other studies and current treatment practices, a panel of experts with diverse areas of scientific and therapeutic expertise will be brought together over the next several months. Awaiting the recommendations of this panel, the NHLBI regards it prudent practice at this time to:

- Initiate treatment of mild high blood pressure, particularly in the range of 90-94 mm hg, with non-pharmacologic measures as long as this treatment is effective in maintaining normal blood pressure. (It should be noted that the efficacy of non-pharmacologic treatment on a large scale basis has not yet been demonstrated).

- Pharmacologic treatment, as used in HDFP, should be considered when other treatments are not effective in maintaining blood pressure control, even in those subgroups with abnormal resting ECGs.

- In general, it is prudent medical therapy to use the lowest dosage of any drug effective in maintaining control.

Regarding diuretics, a dosage of 50 mg daily of hydrochlorothiazide (or its equivalent) should probably not be exceeded.

- In the subgroups of patients with resting ECG abnormalities, addition or substitutions of other approved antihypertensive agents may be warranted if diuretics in low dosage (e.g. hydrochlorothiazide 25-50 mg daily) are not adequate to control the blood pressure.

- Appropriate monitoring of serum potassium levels is warranted, as always.

PERFLUOROCHEMICALS

Question: How soon will this blood substitute be available to the public for general use--and hasn't it already been used?

Answer: During the past two years, a commercially prepared perfluorochemical substitute, Fluosol-DA, has been undergoing human clinical trials for safety and efficacy. It is anticipated that the manufacturer will submit a new drug application to the FDA within the next few months seeking approval to market the product. It will be used as a red blood cell substitute in patients suffering from acute blood loss. The manufacturer is also in the process of initiating human clinical trials with Fluosol-DA to test the ability of this product to reduce tissue damage following myocardial infarction.

Question: What are the advantages and disadvantages of the substitute--and in what type of medical situations would it be most helpful?

Answer: Perfluorochemical emulsions such as Fluosol-DA display excellent promise as substitutes for the oxygen-carrying capacity of red cells. Stromafree hemoglobin solutions, another class of substitutes, also show promise but are still several years away from clinical studies in humans. Fluosol-DA has been studied in humans with myocardial infarction, anemia, and hypovolemic shock; some clinical trials are already underway. There have been promising studies in animals with stroke, carbon monoxide poisoning, cerebral vasqspasm, cerebral ischemia, as well as the using Fluosol-DA as an adjunct to chemotherapy and ionizing radiation. With the information from the human clinical trials, the manufacturer believes that enough favorable safety and efficacy data have accumulated to submit a new drug application to the FDA.

Perfluorochemicals, while promising, still have their own unique set of problems. A major disadvantage with Fluosol-DA is that its half-life in the liver and spleen is at least 60 days and perhaps longer. Most investigators believe that such long-term retention is unacceptable, although long-term effects are still unknown. The high concentrations of oxygen (approximately 60 to 100 percent) that must be administered to the patient receiving the Fluosol-DA is another shortcoming. And finally, for Fluosol-DA to remain stable, it must be stored in the frozen state. It would be preferable to store emulsions at room temperature or at 4°C.

Question: What studies are you conducting, or planning to conduct, on the substitute?

Answer: We are currently assessing two new perfluorochemical compounds that were synthesized under previously sponsored NHLBI contracts. One of the compounds, perfluorobicyclononane appears very promising and may be superior to existing perfluorochemical compounds.

Also, the blood division is sponsoring a number of grants in which investigators are using perfluorochemical compounds as research tools to answer fundamental and applied biological questions. Examples of such studies are listed below:

1) Studies of the effect of certain perfluorochemicals on the in vitro preservation of human organs for subsequent transplantation.

2) Studies of capillary permeability with perfluorochemical emulsions.

3) Studies to determine the extent to which perfluorochemical emulsions can accelerate the restoration of myocardial function following coronary flow reduction.

4) Studies using perfluorochemical emulsions of defined particle size as models of platelets and chylomicra to obtain a comprehensive understanding of blood cell effects in flowing blood.

5) Studies to evaluate the potential therapeutic effectiveness of perfluorochemicals in preventing or reducing central nervous system metabolic damage caused by cerebrovascular pathology.

BYPASS SURGERY

Question: We continue to be concerned about the efficacy of coronary bypass surgery. According to one source, as much as $2 billion may have been spent in the U.S. last year on bypass operations. What is your current thinking on this type of procedure and its usefulness in both extending life and improving the quality of life for coronary patients?

Answer: Coronary artery bypass surgery is unquestionably of benefit in prolonging life as well as improving the quality of life. It relieves or improves angina in 70-80% of patients. Bypass surgery has, therefore, been used since the late 1960's to relieve angina in severely symptomatic patients. Relief of angina is accompanied by improvement in more objective indications of improved coronary blood flow such as increased exercise capacity and reduction in exercise induced ECG abnormalities. Three randomized, controlled clinical trials, the European Cooperative Study, the Veterans Administration Study, and the Coronary Artery Surgery Study (CASS), were designed to assess the effect of bypass surgery on long-term mortality. The first two trials have reported results. CASS, an NHLBI supported trial, will report results in the fall of 1983.

The results of the first two trials are congruent in some subsets of patients but not others. Patient subsets in which the results are concordant include the following: Bypass surgery

improves longevity in patients with left main coronary artery stenosis. Bypass surgery does not improve longevity in patients with single vessel coronary disease.

Cognizant authorities agree generally in these two subsets. There is generally less agreement in the two other categories of patients, those with double vessel and triple vessel disease. It is anticipated that CASS results will clarify indications in these remaining important subsets.

Question: We understand that lasers have been used to vaporize the buildup of plaque inside blood vessels -- the underlying cause of most heart attacks and strokes. What can you tell us about this?

Answer: Laser energy can be carried by optical fibers through catheters designed for intravascular use. Obstructive atherosclerotic lesions in the coronary, carotid, renal, and peripheral vasculature might be vaporized by carefully directed application of laser energy.

The effect of laser application has been assessed in animal arteries and human necropsy material. A variety of laser sources have been used, including CO2, Nd-YAG, and Argon. Laser energy does vaporize atherosclerotic lesions and components of the arterial wall.

Further detailed animal studies will be needed prior to human application to determine energy setting, optimum laser source, mechanism for aiming the laser, and controlling the extent of injury.

An additional concern is the possibility that arterial injury might lead to accelerated atherosclerosis.

Initial human studies are at least a year away, and will probably occur in the operative setting with coronary arteries which are to be bypassed with saphenous vein grafts. Catheter application in humans is probably 2-3 years distant since the means of positioning and aiming the laser intravascularly are more difficult and offer more potential for arterial perforation with catastrophic sequelae.

PACEMAKERS

Question: We have heard of the possibility that some persons who don't need them have had pacemakers implanted in their chests. What advice should doctors give their heart patients on whether they should have a pacemaker implanted?

Answer: Permanent implantable pacemakers, first used in 1960, are truly a lifesaving device in some patients; for example, patients with syncope and complete heart block. Pacemaker technology has improved greatly over the past 20 years with the introduction of improved power sources, lead systems, and circuitry which permits physicians to tailor pacemaker performance to each patient's needs.

The principal indication for pacemaker implantation is still symptomatic complete heart block which may be due to a variety of cardiac disease processes including coronary artery disease and,

perhaps most importantly, sick sinus syndrome, a degenerative process involving the cardiac electrical system (called sinus syndrome).

Question: Should a second opinion be sought out in the same way it's now recommended that people get a second opinion before undergoing surgery?

Answer: Knowledgeable physicians generally agree upon the indications for pacemaker implantation. Patients who doubt their physician's competence to recommend pacemaker implantation should seek a second opinion.

FUNDING OF APPROVED GRANTS

Question: What proportion of meritorious research applications received by NHLBI last year were funded?

Answer: Of 2,153 research project grant applications approved by the peer review process in FY 83, about 734 or 34 percent were funded.

Question: How does this compare to five years ago?

Answer: Of 1,625 research project grant applications approved by the peer review process in FY 78, 759 or 47% were funded.

UNFUNDED OPPORTUNITIES

Question: Can you cite major research opportunities in heart, lung, and blood that have not been funded in recent years as a result of limited resources?

Answer: The National Heart, Lung, and Blood Institute (NHLBI) has a number of meritorious and promising program opportunities that it has to date been unable to fund. With the funds available, the Institute funds the research believed to have the greatest potential contribution to continued national progress in the prevention, diagnosis, and treatment of diseases of the heart, lungs, and blood. There are many promising research leads and, unless research funds were virtually unlimited, not all such research could be supported. Examples of unfunded research opportunities include studies of atherogenesis using new techniques of molecular and cellular biology; fundamental and applied studies of disordered heart rhythms; certain collaborative studies on Acquired Immune Deficiency Syndrome, and a clinical trial on early detection of Chronic Obstructive Pulmonary Disease.

LUNG RESEARCH

Question: What major research breakthroughs on lung disease are on the horizon?

Answer: Several areas of lung research promise to yield new and important information leading to better understanding of normal lung function, and to elucidation of the pathogenesis, diagnosis, and treatment of lung diseases. The new focus on lung cell biology, for example, has provided a wealth of information which is relevant not only to understanding of the normal lung, but to knowledge of lung diseases as well. The role of the pulmonary endothelial cells

which line the blood vessels, in processing circulating vasoactive substances, drugs, and other compounds continues to be actively investigated; the full range of substances metabolized by these cells is not yet known. The clinical implications of these activities are also not yet clear. How these activities are altered in the injured lung, for example in pulmonary hypertension or in patients receiving prolonged oxygen therapy, also must be addressed. The role of the pulmonary endothelium in initiation of the immune response or in an anaphylactic shock is another promising area of research.

The epithelium of the mammalian respiratory tract contains a scattered population of secretory endocrine-like cells, (also called APUD cells), which are receiving increasing interest and attention. Histochemical and immuno-histochemical studies suggest the presence of a variety of amines and peptides in the lung endocrine cells. It is possible that several types of lung endocrine cells exist, and that they perform a variety of functions, inluding the secretion of sustances regulating bronchial smooth muscle tone and controlling the pulmonary circulation. They may also, as part of their secretory function, influence processes in other organs. The function of these cells in fetal and neonatal lung is also of great interest. The study of the substances secreted by certain lung cancers may provide clues about the function of the endocrine cells in normal lung. In turn, increased knowledge of the basic biology of the lung endocrine cell may yield information that can be applied to the treatment of these diseases.

Another area of interest is the study of lung cell-to-cell interactions. Recent studies have suggested that endothelial cells play an active role in the initiation of the immune response by interacting with T lymphocytes. How pulmonary alveolar macrophages and lymphocytes interact with connective tissue cells (fibroblasts), and the implications of this for diseases such as lung fibrosis are not known. The importance of cell-to-cell interactions to other processes such as synthesis of prostaglandins (compounds which are provided and metabolized by the lung, and which have potent effects on smooth muscle contraction, blood pressure and blood clotting), and in the repair process following lung injury also need to be addressed.

The investiation of the immunologic function of the lung is another area of growing interest. Recent work suggests that the synthesis of the blood component, complement proteins, by pulmonary alveolar macrophages is altered in patients with pulmonary disease. The clinical significance of these findings is not clear. Other recent work is concerned with recruitment of T lymphocytes to the lung following exposure to influenza virus. These and other related studies may lead to important clues to the pathology and therapy of lung diseases.

LIVES SAVED

Question: How many lives could be saved each year by the medical professional as a result of accelerated increases in funding for research at NHLBI?

Answer: During the 10-year period 1962-1972, when the Institute budget increased from $100 million to $200 million, the

cardiovascular disease death rate declined an average of 1.4% per year. During the ten years 1972 to 1982 the budget increased to about $500 million per year and the death rate declined an average of 2.9% per year, representing 32,000 lives saved each year. This decline is unprecedented in both its magnitude and duration so one cannot say with certainty that further acceleration of this rate of decline can be achieved.

Question: How can NHLBI and the Health Care Community improve on the actual implementation of clinical application of research?

Answer: There is always a need to strengthen our ties to the practicing community. We are fortunate in being able to draw upon our experiences with the national effort to control high blood pressure when we plan for the transfer and translation of research findings. That effort, as you may be aware, relies heavily on intermediary groups. Medical organizations such as the American Medical Association, the National Medical Association, the American College of Cardiology, the American College of Preventive Medicine and many others serve on the coordinating committee of the national program as do voluntary organizations such as the American Heart Association and the American Red Cross. Information resulting from research which has a bearing on the control of high blood pressure is funneled through these organizations to their memberships and to the public (or patients).

The lesson learned in the national high blood pressure effort is to identify organizations to form a network which has a special interest in or concern with a particular health problem, a certain disease, or a specific population or patient population. Establishing contact and involving these organizations in the dissemination of research findings is often a very productive way of seeing that research findings are applied when warranted.

This networking process is not proposed as a replacement for some of the more conventional means of disseminating information, such as journal articles or professional meetings. Rather, it should be viewed as an additional channel, one which requires a considerable time investment but one which can be exceptionally productive.

CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Question: The Lung Community talks about, in the face of an aging population, the need to make major new initiatives against Chronic Obstructive Pulmonary Diseases. Do you agree and can you tell us some of the Chronic Obstructive Pulmonary Diseases research activities that are being conducted at NHLBI.

Answer: More than nine million Americans are thought to have chronic obstructive pulmonary diseases (COPD). Since 1968 COPD has been the fastest rising major cause of death in the United States. In 1978 there were more than 44,000 deaths, approximately 14 per 100,000 people. Epidemiologic studies conducted over the past 15 years have indicated that, although lung function declines with age, the decline is much more rapid in those who smoke. In fact, smoking is the major risk factor for abnormal decline in pulmonary function and subsequent development of COPD. Moreover, individuals with hyperactive airways are at increased risk for a more rapid decline than those without hyperactive airways.

Although these risk factors in the development of COPD have been identified, it has not been prospectively shown that elimination of risk factors will result in the prevention of COPD. Yet it is possible that early identification, the elimination of smoking, and the administration of bronchodilators to those with hyperactive airways may lessen this abnormal decline associated with COPD.

The Division of Lung Diseases began a major new initiative in FY 1983 to establish whether early identification and intervention can prevent rapid decline in those with abnormalities in pulmonary function. If this clinical trial shows that COPD can be prevented, the results could hold significance for wide public health applications. Although this trial will be a large one, requiring thousands of subjects, the potential is great for reducing the number of people who develop this disabling condition.

LUNG RESEARCH

Question: Some in the lung field are urging more effective coordination and review of lung research in all Federal Agencies. Do you agree with this thinking?

Answer: Yes, we do. While the National Heart, Lung, and Blood Institute is the lead agency for the federal research effort in lung diseases, at least 20 other government agencies support the national research effort. Within the National Institutes of Health (NIH), National Institute of Child Health and Human Development (NICHD) supports work in the area of pediatric lung diseases, National Institute of Allergy and Infectious Diseases (NIAID) in infectious and immunologic lung disorders, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) in cystic fibrosis, National Cancer Institue (NCI) in lung cancer, and National Institute of Environmental Health Statistics (NIEHS) in lung disorders resulting from environmental pollutants. Agencies outside the NIH with significant involvement in lung diseases include the Veterans Administration, the Department of Energy, the Environmental Protection Agency, and the Department of Defense, to name just a few. It is clear that coordination of these diverse elements is essential to achieve a balanced and effective national program.

Question: With this in mind, does this initiative appear to be a way in which great benefit can be derived at a relatively small cost?

Yes, it does. The coordination of this diverse involvement has significant benefits for the national program, as well as for the individual federal agencies contributing to it. Areas that warrant greater emphasis can be identified and the roles of various agencies in pursuing these new thrusts can be delineated; unnecessary duplication of effort is minimized; the overall impact of efforts can be assessed from multiple perspectives; and agency planning and program management can be facilitated. Further, the broad, long-range goals of the national lung program provide many opportunities for cooperative/collaborative efforts among these organizations. Such efforts would allow for efficient utilization of available resources and extension of the program to encompass many related activities which further the missions of both the National Heart, Lung, and Blood Institute and other federal organizations.

An administrative structure for this effort already exists--namely, the Interagency Technical Committee (IATC) on Heart, Blood Vessel, Lung, and Blood Disorders, which includes in its membership representatives from 16 federal agencies. Plans are underway to establish within the IATC a new Subcommittee on Lung Diseases, which would be charged with developing a coordinated plan for the National Institutes of Health and other federal lung programs, assessing the adequacy of management approaches for these activities monitoring and reviewing expenditures by the agencies involved, and identifying research and training activities in the pulmonary area.

Question Submitted by Senator William Proxmire

RESEARCH CONTRACTS

Question: Dr. Lenfant, the table on page 84 of your justifications indicates that you don't plan to award any new research and development contracts next year after providing $7,232,000 for this purpose in the current fiscal year. Have you decided to phase out your contract operations?

Answer: No, we are not phasing out our contract operations. The 1984 budget allows the National Heart, Lung, and Blood Institute to continue support of ongoing clinical trials; analyses of recently completed trials; the circulatory assist/artifical heart program; the National High Blood Pressure Education Program; and other similar high priority programs which receive their support from research contract funds.

NATIONAL INSTITUTE OF DENTAL RESEARCH

STATEMENT OF HARALD LÖE, DIRECTOR

ACCOMPANIED BY:

JOHN F. GOGGINS, DEPUTY DIRECTOR, NIDR
DR. JAMES B. WYNGAARDEN, DIRECTOR, NIH
NORMAN D. MANSFIELD, DIRECTOR, DIVISION OF FINANCIAL MANAGEMENT, NIH
ANTHONY ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET, DHHS

BUDGET REQUEST

Senator WEICKER. Next, we will hear from the National Institute of Dental Research which has a far smaller budget than Cancer or Heart and Lung, but which conducts some very critical research.

The budget request for the Dental Institute is $80.6 million, just about the same amount requested in January and almost $2 million more than the fiscal 1983 level.

Here to testify in support of the Dental Institute budget is Dr. Harald Löe, who is making his first appearance before the subcommittee as the new Director.

I remember Dr. Löe as dean of the School of Dental Medicine at the University of Connecticut at Farmington. And a warm welcome to you, sir.

Dr. LÖE. Thank you very much, Mr. Chairman.

You have already heard from the other Institute Directors that we find ourselves in the midst of a biomedical revolution, and that technical advances in the past few years are having a dramatic impact on man's life and longevity. Dental medicine has its share of these achievements.

After centuries of steady increases, tooth decay, or caries, is now showing a drastic decline. More children are caries free. Young adults require less restorative care, and tooth mortality rates are declining.

Apart from the obvious dental health benefits, these developments are not without national economic impact. It has been estimated that the reduction in caries alone reduced the Nation's total dental care bill for 1981 by approximately $2 billion. This 1-year savings represents more than twice the cumulative amount of money appropriated for the NIDR in its entire 35-year existence.

This reduction in caries prevalence, we believe, is primarily the result of the last two decades of research on caries prevention in general, and the effect of fluorides in particular, for which the NIDR can take much pride.

Among other major activities and accomplishments, I would like to highlight the following:

Progress continues in the development of a miniature device designed for slow release of fluoride in the human mouth. This device will be particularly helpful in special populations for whom the usual methods of fluoride applications are impractical or impossible.

The work on the vaccine against caries continues and has reached a stage where clinical tests are imminent.

A breakthrough in restorative materials research involves a new process of bonding plastic filling materials to dentin. Clinical application of this research would require removal of much less tooth structure before restoration. There will be less drilling, treatment time will be reduced, and patient comfort will be greatly enhanced.

Exciting developments in pain research begun in the Dental Institute are now at the stage where useful applications are available for clinical testing. A new pain research unit located in the Clinical Center will serve all Institutes, not only for studies of the control of dental pain, but also for chronic pain in relation to cancer, diabetes, and arthritis.

We are now in the final stage of completing the NIDR long-range research plan. It is clear from the draft material of this plan that there are several areas of critical need and scientific opportunity. The changing demographic profile of the American population and shifts in disease prevalence necessitate an update on the epidemiology of the major dental diseases and conditions in the American public.

So far, most of our efforts have been in the prevention of oral diseases in the young. Since large numbers of our citizens now have the opportunity to live longer and fuller lives, however, we may be faced with a whole new set of oral health problems. We need to know what these problems are, how they are distributed, and how to cope with them, or, better yet, how to prevent them.

Mr. Chairman, it is my assessment, since assuming the directorship of the NIDR, that the Institute is making great strides in understanding the nature of oral diseases and conditions, in focusing on the areas of critical need, in seeking new knowledge, and in clinical testing of laboratory developments.

NIDR is the world's foremost research institute in dental science. And it is my firm objective to maintain that destinction.

I shall be pleased to answer any questions you may have.

Senator WEICKER. Thank you very much, Dr. Löe.

Let me start off with the same question I asked the other Institutes.

Dr. LÖE. May I say, Mr. Chairman, that with me today is the Deputy Director, Dr. John Goggins.

Senator WEICKER. Nice to have you with us.

Insofar as the competing grants are concerned, how will the increase in the number of new and competing grants affect your Institute?

Dr. LÖE. Yes.

Senator WEICKER. Numbers first of all, just numbers.

Dr. LÖE. Under the current budget proposal, we plan to support 134 new and competing grants. We have a portfolio of approximately 385 competing and noncompeting grants.

There is one difference between our Institute and some of the others. We fund very few program project grants which are usually larger. As a result, the average cost of our grants over the last few years has always been smaller than the NIH average grant. This is not a new situation for us.

We are stretching our resources a little further, but we have tried over the years to fund as many new research grants as possible at the expense of some of the bigger program project grants.

Senator WEICKER. So in the case of your Institute, the policy of greater numbers and fewer dollars would seem to fit better; would that be right?

Dr. LÖE. Well, I am not sure that it fits better, but it is a defacto matter.

Senator WEICKER. Again, what about the research centers? Do they apply in any case to your Institute?

Dr. LÖE. Yes.

Senator WEICKER. They do?

Dr. LÖE. We have five noncategorical centers around the country and three periodontal research centers. We plan, as you can see from the budget, to support all eight of them. We will have to see the results of an evaluation of the centers up for renewal to determine whether there will be a cut across the board for all eight or the evaluation process will indicate something else. We have some flexibility in that situation.

Senator WEICKER. But in any event, flexibility in terms of who is going to participate in the cut, but there is going to be a cut.

Dr. LÖE. There is a reduction in centers of $1.5 million.

Senator WEICKER. More than that. I have got $2.2 million.

Dr. LÖE. It is less than $2 million.

Senator WEICKER. I just want to clear that up on my sheet. The 1984 amount would be down $2.2 million; am I correct in that?

Dr. LÖE. The figure I have for 1984 is $7,565,000.

Senator WEICKER. Right. Down from——

Dr. LÖE. From $9,325,000.

Senator WEICKER. The President's original budget had $9.8 million. It has been reduced to $7.5 million for a change of $2.2 million. Am I correct on that?

Dr. LÖE. Yes, you are correct. I am looking at the change from the 1983 figures.

Senator WEICKER. You mention the caries vaccine. When would you expect the vaccine to be completed and available for mass use?

Dr. LÖE. Let me first say that I am not sure that a vaccine is going to be for mass use. I think we have made significant progress through other preventive methods.

As I said in my introductory statement, one-third of the young people in this country are caries-free with the current methods of preven-

tion. A vaccine will probably address some of the problems in patients over and beyond what we can do with the other simple methods of preventing caries. A caries vaccine is close to reaching the point of clinical testing. Although I can't give you a date for when a vaccine will be on the market, there is a definite possibility for a vaccine against caries.

Senator WEICKER. I am personally past the point probably where I care that much; it is all those little kids out there that are terrified of going to the dentist. They are the ones. What you have to find for me somehow is how to make root canal painless, and I would be in great shape.

Dr. LÖE. I wouldn't be too sure about that, Senator. We are discovering that as we grow older, and we are going to grow older, there is a type of caries becoming more prevalent. I am referring to root caries, which is basically a caries lesion affecting older individuals. It constitutes a different problem than coronal caries for the dentist. Root caries is much more complex in terms of its treatment. We plan to get on with research in this area, both on its cause and prevention.

Caries is now only a problem in the young, but it becomes a real problem in the increasing number of elderly.

Senator WEICKER. Herpes of the cold sore variety gets understandably less attention these days than does genital herpes. Nevertheless, people who suffer from the less debilitating form of herpes need reassurance that you are doing something about their problem.

What progress are we making against the herpes simplex virus? And what drugs have been found to be effective in this area?

Dr. LÖE. One new development is the application of a method called iontophoresis to deliver antiviral substances through the tissues in order to reach the virus. There seems to be significant promise with that type of treatment. Another of our major efforts is to attempt to prevent the primary infection of the herpes virus type I which relates to the mouth. Our effort is concentrated more on developing a vaccine against herpes.

Type I and type II are closely related to each other in terms of structure. So whatever controls type I virus may have impact on type II and vice versa. So there is a joint effort among many of the Institutes to reach the same goal. We are actively engaged in all parts of the program. At the moment, work is concentrated on purifying some of the proteins that may serve as antigens for immunization against herpes. We are not at the stage clincially where a vaccine is available commercially. That is further down the road.

PREPARED STATEMENT AND SUBMITTED QUESTIONS

Senator WEICKER. Dr. Löe, I have further questions for response to the record.

Thank you very much for appearing before the committee. And good luck to you.

Dr. LÖE. Thank you very much.

[The information follows:]

Statement of Dr. Harald Löe

I welcome this opportunity, my first since becoming the Director of the National Institute of Dental Research, to describe to you the accomplishments made by the Institute during the past year and to outline some of the new directions of study we plan to pursue in the coming year.

To guide the Federal investment in oral and dental research in areas of greatest need and most promising scientific opportunity, the Institute staff and consultants are developing a long-range research plan. The plan, which will be completed this year and will be updated periodically, exploits those areas of research with the greatest potential for success as based on current scientific knowledge. It is against the background of this plan that my presentation today is made to you.

Dental Caries

The recent survey conducted by the NIDR's Caries Program clearly shows that the prevalence of dental caries, or tooth decay, among U.S. school children has decreased more than 30 percent in the last 10 years, and that more children are now totally caries free. This is a significant achievement, possibly indicating that, after centuries of increase, dental decay--for the first time--is on a decline.

There are reasons to believe that this decrease is the result of multiple strategies for the use of fluorides developed over the last several decades. However, for various reasons, tooth decay remains a formidable national problem in children as well as in adults; therefore, imaginative research programs are progressing toward the ultimate elimination of caries.

Progress continues in the development of a miniature device designed to continuously release predetermined levels of fluoride in the mouth. This slow-release device will be particularly helpful in special populations, such as the handicapped and other groups where usual methods of fluoride applications are impractical or impossible. The successful completion of a planned, brief trial in children to monitor characteristics of the fluoride release and safety will be followed by an extended clinical trial to evaluate this means of caries prevention.

Over the years, the Institute has given emphasis to establishing a strong foundation for developing an effective anticaries vaccine. Animals have been successfully immunized against caries, and studies have now demonstrated an antibody response in the saliva of humans following ingestion of a capsule containing the bacterial antigen. Several recently introduced research tools are expected to improve the ability of scientists in this complex area of study to discover the underlying mechanism of secretory immunity and to identify a potent, yet safe, immunogen.

The frequent consumption of starches and sugars is a known contributing factor in the causation of dental caries. Detailed investigations are underway of the particular chemical and physical properties of common snack foods that account for their decay-causing potential. Future research will include a longitudinal study of the

types of foods and the eating patterns that are conducive to the development of caries in school children. Also, animal studies are expected to define the mechanisms by which decay-causing characteristics of foods may be modified. Opportunities exist to work with research and development counterparts in the food industry to find ways to improve American dietary habits for the purpose of reducing caries in all age groups.

Caries on tooth roots, a condition rarely found in children, is becoming a major concern to the adult population. A survey is now planned to attain a better understanding of the relationships of root caries to the demographic shifts that are taking place and to tooth decay and periodontal diseases.

In addition to the laboratory, clinical, and field studies of the Caries program, efforts continue to provide the general public as well as health professionals with information on current research and effective techniques in caries prevention. Research on effective and efficient ways to improve this technology transfer supports the effort to provide useful facts about available, cost-effective caries prevention programs to state and community leaders in implementing and conducting school based, self-applied fluoride programs.

Periodontal Diseases

Periodontal diseases are disorders that destroy the bone and soft tissues that support the teeth. It is now clearly established that these disorders are inflammatory diseases initiated by the action of bacteria which colonize the gum tissues. If left unchecked, these massive accumulations of microorganisms, called bacterial plaque, will gain entrance between the gums and teeth and/or invade the tissues, and slowly, but steadily destroy the attachment of the teeth, causing loosening and, ultimately, loss of the teeth.

As a rule, periodontal inflammation starts in early adulthood and increases in severity with advancing age. One consequence of improved caries control is that more teeth than ever are retained by adults and are therefore subject to periodontal diseases. Thus, periodontal diseases are rapidly becoming the principal dental public health problem.

The last two decades have seen significant advancement in the research on these diseases. New microbiological and immunological techniques have elucidated the complexitites of the bacterial infection and the intricacies of the host tissue response. It is now clear that different pathogenic bacteria are associated with different types and severities of these diseases. Recent data show that one single microorganism is implicated in an extremely severe and rapidly advancing form of periodontal disease that occurs in teenagers. Preliminary evidence also suggests that a similar specificity may occur in periodontal diseases associated with juvenile onset diabetes.

Such findings open new pathways of investigation that may lead to improved preventive approaches and eventual control of periodontal diseases. As of the moment, the basic approach to the prevention and treatment of periodontal diseases focuses on mechanical removal of the bacterial plaques from the teeth at intervals by the patients

themselves or by professionals. Although studies indicate that it is indeed possible to maintain healthy supporting tissues through vigorous home-care or frequent dental appointments, it is generally agreed that new and improved technologies for diagnosis, prevention, and treatment of periodontal diseases are in order.

Recent evidence suggest that, as periodontal destruction advances, active progression is intermittently interrupted by periods of quiessence. To plan appropriately clinical management for periodontal patients, we need to develop objective diagnostic procedures that are able to differentiate between active and non-active disease. Identification of a new, hormone-like factor in material emanating from the gums around inflamed teeth may lead to improved methods of early diagnosis of susceptible patients.

Periodontal therapy, in most instances, will arrest the disease. However, bone loss has been considered irreversible. Now, recent investigations indicate that implanting newly developed bone-growth-inducing substances may stimulate regeneration and repair of bony defects that occur as a result of periodontal diseases. The periodontal diseases pose a very special challenge to dental researchers. There are clearly new leads and opportunities, which, with increased efforts, could drasticaly enhance the health and longevity of human teeth. The long-range research plan for the NIDR when completed this summer will speak to these challenges.

Soft Tissue Stomatology

The soft tissues of the oral cavity, including the lips, are the sites of the painful and recurrent herpes simplex virus infections--fever blisters and cold sores. Clinical studies are in progress that involve a method of delivering drugs through the skin in sufficient concentration to kill the herpesvirus. Results to date show that a noticeable reduction in pain and in the duration of such conditions is achieved when patients are treated at an early stage of infection with an antiviral drug and a procedure known as iontophoresis, which propels the drug by a weak electric current into the infected area.

The prospects of developing an effective vaccine against primary herpes infections have been greatly enhanced by the improvement of methods of purifying viral proteins and the use of new technologies leading to mass production of specific immunizing proteins.

Recent investigations have revealed that cancers of the oral cavity have an inflammatory base long before ulceration within the mouth or any other symptoms are observed. The reliability of using the dye toluidine blue as a technique for early diagnosis of oral cancer is being evaluated. While results now show a high degree of reliability, further research may provide improvements in early detection and diagnosis of oral cancerous lesions.

Craniofacial Anomalies

With a reported 10.5 million new head injuries each year, new insights must be gained on growth processes and on the maintenance and repair of craniofacial tissues. Research findings on wound healing assist in determining the rate of healing and the quality of repair. The number of cells present in wounds can be increased by

the direct application of substances that alter cellular migration and proliferation. In recently initiated studies of cleft lip and palate in humans, newly devised methods in genetic epidemiology are being employed to determine why races differ in the incidence and type of oral clefts. The research is designed to evaluate the influence of major genes, to test whether their influence varies between ethnic groups, and to determine whether there are environmental factors related to ethnic groups that affect the outcome of pregnancy.

Pain

Pain sensation normally serve as a signal of impending or already present tissue damage. Three distinct classes of facial nerve fibers that transmit pain impulses to the central nervous system have been identified. Scientists have now described much of the ultrastructural organization of the nerve complex that receives and adjusts the pain signals in oral and facial pain. These and other studies of the perplexing problems in diagnosing oral pain and in developing new therapies continue to provide new knowledge not only on the clinical aspects of dental, oral and facial pain control, but also on the basic mechanisms involved in all pain transmission and modulation.

Behavior

For some oral diseases, preventive measures are available that could greatly reduce the ravages of the condition, particularly dental caries and periodontal diseases. While the technologies are more developed for caries prevention than for periodontal diseases, all depend upon their effective application either by health professionals or by the public. Behavioral research focused on understanding the factors influencing how the dental profession and administrators accept and use these technologies and the factors associated with the acceptance and use by the public, is essential in effectively transferring what is now know to the American people.

Restorative Materials

Through the years, dental research has made significant advances in the development of synthetic adhesives that successfuly bond to tooth surfaces. Such materials that bond to tooth enamel are now available for wide use in dental practice. Achieving adhesive bonding to dentin-- the porous inner core of teeth--has presented researchers with a much more difficult problem. However, a new procedure has been perfected that treats the exposed surface of dentin with chemicals prior to applying a composite resin mix. This technique promises to revolutionize certain aspects of restorative dentistry, simplify the technology in restoring teeth, improve esthetics, and reduce cost.

Several promising alloy systems that contain only small amounts of precious metal are also being tested. The ultimate goal of these programs is to provide the dental profession with restorative materials less expensive than those containing gold, yet superior in strength and durability.

It is very clear to me as I assume the leadership of the National Institute of Dental Research that the programs supported by

this Institute are dynamic and vibrant, and hold unprecedented challenges and opportunities for the future as we seek a better understanding of the nature of oral health and disease. By our gains, we can hope to alleviate, prevent, or control some of the most complex, serious, yet common diseases afflicting mankind.

The budget request for 1984 is $80,679,000. I shall be pleased to answer any questions you may have.

Biography of Dr. Harald Löe

NAME: Harald Löe

POSITION: Director, National Institute of Dental Research, NIH

BIRTHPLACE AND DATE Steinkjer, Norway; July 19, 1926

CITIZENSHIP: United States

EDUCATION:
D.D.S., Oslo University, Norway, 1952
Dr. Odont., Oslo University, Norway, 1961

EXPERIENCE:
Dean and Professor of Periodontology, School of Dental Medicine, University of Connecticut, Farmington, Connecticut,
1974-1982

Professor of Dentistry and Director of the Dental Research Institute, University of Michigan, Ann Arbor, Michigan,
1972-1974

Associate Dean and Dean-elect, Royal Dental College, Aarhus, Denmark,
1971-1972

Professor of Dentistry and Chairman, Department of Periodontology, Royal Dental College, Aarhus, Denmark,
1962-1972

Visiting Professor of Periodontics, Hebrew University, Jerusalem, Israel,
1966-1967

Associate Professor, Department of Periodontology, School of Dentistry, Oslo University, Norway,
1960-1961

University Research Fellow, Oslo University, Norway,
1959-1962

Fulbright Research Fellow and Research Associate, Department of Oral Pathology, University of Illinois, Chicago,
1957-1958

Research Associate, Norwegian Institute for Dental Research, Oslo, Norway,
1956-1962

Instructor in Operative Dentistry, School of Dentistry, Oslo University, Norway,
1952-1955

ASSOCIATION MEMBERSHIPS:
American Dental Association (ADA)
American Academy of Periodontology (AAP)
American Association for Dental Research (AADR)
Danish Dental Association
International Association for Dental Research (IADR)

IADR Periodontal Research Group
Norwegian Dental Association
Scandinavian Association for Dental Research
Sigma XI, The Scientific Research Society

SPECIAL AWARDS, CITATIONS, OR PUBLICATIONS:

Norwegian Dental Association 75th Anniversary Prize, 1959
Ingv. Stokke Prize for Outstanding Dental Research, Oslo, Norway
Erik Berg Foundation Prize of Honor, Copenhagen, Denmark, 1965
Honarary Member, Milwaukee Dental Forum, U.S.A., 1965
Corr. Member, Swedish Dental Association, 1966
Honorary Member, Colombian Society of Periodontology, Colombia, South America, 1968
Honorary Member, Western Society of Periodontology, Denmark, 1969
Aalborg Dental Society Prize of Honour, Denmark, 1969
International Association for Dental Research Award for Basic Research in Periodontics, 1969
Honorary Member, Cercle de Parodontie, France, 1970
Honorary Member, South African Society of Periodontology, 1972
American Society of Preventive Dentistry International Award, 1972
Honored by Her Majesty the Queen of Denmark (Knights of Danebrog), 1972
Honorary Doctorate, University of Gothenburg, Sweden, 1973
Massachusetts Dental Society International Award, 1973
Corr. Member, Finnish Dental Society, 1974
Honorary Member, Horace Wells Club, Hartford Connecticut, 1976
Certificate of Achievement, Connecticut Society of Periodontists, 1976
Honorary Member, Centro de Estudios de Recursos Odontologicos para el Nino (CERON), 1978
Fellow, International College of Dentists, 1978
William J. Gies Periodontology Award, 1978
Fellow, American College of Dentists, 1980
Honorary Doctorate, Royal Dental College, Aarhus, Denmark, 1980
Honorary Doctorate, University of Athens, Greece, 1980
Honorary Doctorate, Catholic University of Leuven, Belgium, 1980
Fellow, American Association for the Advancement of Science (AAAS), 1981
Honorary Member, Scandinavian Society of Periodontology, 1981
Corr. Member, Swiss Periodontal Society, 1982
Honorary Member, Societe Francaise de Parodontologie, 1982
Honorary Member, Belgian Society of Periodontology, 1982
Award of Merit, Hartford Dental Society, 1982
Citation, University of California School of Dentistry Centennial Commencement, 1982
Gold Medal, University of Ghent, Belgium, 1982

Questions Submitted by the Subcommittee

Question: We would like to get your perspective on how the revised NIH budget for FY 1984 affects your Institute. How many additional new and competing grants will you get above the January budget -- and what further research will you be able to do as a result?

Answer: The Institute will be able to fund 38 additional new and competing grants in the revised budget. These additional grants will fund new research in caries, periodontal diseases, restorative materials, craniofacial anomalies, pain control and behavioral studies, and soft tissue stomatology and nutrition.

Question: It is our understanding that the January and April budgets both assume cuts in the average award for new and competing grants below what the full average cost would be. For new grants this appears to be a difference of some $17,800 ($142,400 full cost vs. $124,600 in revised budget). How will this affect your Institute -- and to what extent will it start changing the scope and quality of the projects that are reviewed by your study sections?

Answer: Under the revised budget, the average cost for new and competing NIDR grants is $3,855 below the average cost in the January budget ($104,385 in the January budget vs. $100,530 in the revised budget). While this reduction will limit the scope of the research projects and slow progress to a degree, it will still allow an adequate level of funding to provide new and vital information about oral diseases. This average cost in the revised 1984 budget is 7% higher than the 1983 average cost, offset by the indirect cost reduction of about 3%.

Question: Under your budget revision, the average NIH noncompeting grant award will decrease by about $12,400 below what the full average cost would be ($143,100 full cost vs. $130,700 in budget revision). How will this affect your Institute -- and to what extent will it change the scope and quality of the projects that are reviewed by your study sections?

Answer: Under the budget revision, the average NIDR noncompeting grant will decrease by about $1,000 below the average cost in the January budget ($99,964 in the January budget vs. $98,964 in the budget revision). During 1984, decreases in the overall average cost of noncompeting grants will be accomplished by negotiations with each grantee to affect economies where possible while maintaining the scope and quality of the reserch effort. The average cost in the 1984 revised budget is an increase of about 5% over the 1983 cost, offset by the reduction in indirect cost of about 3%.

Question: The Administration proposes to make cuts from the January budget in grants to specialized and comprehensive research centers. How does this affect your program -- and what will it do to research at those centers? (Request a list of centers that will be affected.)

Answer: The NIDR currently supports five comprehensive university-based centers and three specialized periodontal clinical research centers.

The comprehensive centers have developed a number of highly productive basic science research teams which have sustained records of exemplary performance both in the quality and magnitude of their research. Under proposed budget, the NIDR plans to maintain support for all centers but at a reduced level. Selected projects within each center will have to be cut back or eliminated. As a result, progress in certain areas will be slowed. The comprehensive dental research centers affected are:

Institute of Dental Research, University of Alabama at Birmingham
Dental Research Institute, University of Michigan
Dental Research Center, University of North Carolina
Center for Oral Health Research, University of Pennsylvania
Center for Research in Oral Biology, University of Washington

The more recently established periodontal clinical research centers have developed well-coordinated laboratory and clinical programs on the microbiology and immunology of periodontal diseases. The proposed cuts will bring about a slight reduction in current activities and will not permit planned expansion. The periodontal centers affected are:

Forsyth Dental Center, Boston
State University of New York, Buffalo
Virginia Commonwealth University, Richmond

Question: To what extent will any clinical trials be affected by the proposed cuts in research and development contracts, and cooperative clinical research?

Answer: The NIDR does not plan to cut research and development contracts in the FY '84 budget. Rather, we propose a slight increase over the FY '83 level ($669,000) from $2,470,000 to $3,139,000.

Question: The new budget proposes to eliminate the 5 percent stipend increase for predoctoral and post-doctoral training, to make further reductions from the January budget in the number of trainees, and to decrease the number of research career awards to promising scientists. What effect will these steps have on your Institute's training program -- and what effect will it have on young people contemplating careers in biomedical research?

Answer: The proposed cuts would not reduce the number of trainees in NIDR programs from the level in the January budget, and would have only minor impact on the immediate research programs.

Question: To what extent will the proposals to reduce funding for General Clinical Research Centers and Biomedical Research Support Grants affect biomedical research in general and your Institute's work in particular?

Answer: The General Clinical Research Center (GCRC) at the University of Pennsylvania is the only GCRC devoted primarily to oral health research. This GCRC provides core services and facilities for a number of collaborative projects supported by NIDR. The proposed budget cut would curtail ongoing projects, including the number of patients to be admitted to certain studies, and would essentially eliminate pilot clinical projects.

The substantial reduction proposed for the Biomedical Research Support Grant program (BRSG) would have an impact on the development of both dental research and dental research manpower -- including young individuals in the initial stages of their career development, established scientists between periods of grant funding, and scientists conducting feasibility projects. However, NIDR grantees may compensate for these lost funds from their own research project grants or seek assistance from their constitution or other sources.

PROTECTING THE INVESTMENT

Question: At a time when many budgets are going down, Congress has been increasing funding of the National Institutes of Health, including your Institute. We are concerned that these scarce resources be carefully and effectively used and that there be no basis for criticism of your management of this money. What assurances can you give us that your Institute is making careful and effective use of the appropriations we provide you?

Answer: The NIDR, along with all Institutes at the NIH, assures careful and effective use of its appropriation through scientific reviews and evaluations of extramural and intramural programs. Competitive selection of most purchases of equipment and supplies, and travel requests and purchases orders are authorized at the associate director level within each program area. In addition, periodic internal and Departmental audits of grants and contracts, as well as routine progress reports on all projects, are required.

Question: Aside from the peer review system, what institutional arrangements do you have that serve to deter waste, fraud or abuse in the handling of federal funds?

Answer: NIDR staff have participated with the NIH in the development of guidelines addressing scientific fraud which will be implemented for both NIH intramural and extramural scientists supported by NIH grant funds. In addition, the NIDR's grants and contracts management function monitors all grants and contracts for compliance with Departmental and NIH policy. The grants and contracts management function conducts both in-house and on-site reviews to monitor the scientific progress and expenditure of funds on all contracts and grants.

CARIES VACCINE

Question: You have been working on development of an anti-caries vaccine for many years. Recently, the Wall Street Journal quoted your Dr. William H. Bowen as saying that experiments on humans show there aren't any "insurmountable roadblocks" to the vaccine. When can we expect the vaccine to be completely developed and available for mass use?

Answer: Because any new vaccine must undergo extensive animal and human studies to establish efficacy and safety, we cannot predict accurately when a vaccine against dental caries will be generally available. We are preparing an application to the Food and Drug Administration to permit the first large scale human trials of such a vaccine to commence in the near future. If successful, these trials will be followed by several additional long-term human studies as required for regulatory approval.

Question: The article indicates that you believe the vaccine will eliminate 90 percent of cavities. That is pretty good, but why not 100 percent?

Answer: We do not expect that a vaccine will eliminate 90% of cavities. All available experimental evidence, derived mostly from animal studies, suggests that protection on the order of 50% would be considered a highly successful outcome. Dental caries is a complex disease which results from interaction among several kinds of bacteria, deficiencies in host defense, and dietary practices. Therefore, for full protection, all three causative factors must be controlled. We believe that a successful anticaries vaccine will be an adjunct to, but not a replacement for, other preventive methods.

Question: We understand that caries of root surfaces is becoming a major concern to people 40 years of age and above. What are you doing to find out more about this problem so as to mount an effective research effort against the disease?

Answer: Because of recent successes in partially preventing dental caries in children, more teeth will be retained into adult life. This fact, together with the increasing average age of the American population, suggests that dental caries in adults, especially root surface caries, will become an increasing public health problem in the coming decades. In anticipation of this, we have begun to implement a comprehensive plan of research into the epidemiology, etiology, and prevention of root surface caries. In the near future, we hope to conduct a major national epidemiological study of the prevalence of caries in adults.

HERPES SIMPLEX I

Question: Herpes of the cold sore variety gets understandably less attention these days than does genital herpes. Nevertheless, people who suffer from the less debilitating form of herpes need reassurance that you're doing something about their problem. What progress are you making against the herpes simplex virus -- and what drugs have been found to be effective in this area?

Answer: We are continuing to make progress toward the development of a vaccine effective against the Type I herpes virus. As with the caries vaccine, it will be several years before it will be available for mass use. In the meantime, we are studying ways of healing cold sores. Limited success has been achieved by applying currently available antiviral drugs. Vidarabine monophosphate (Ara-AMP) and Acyclovir (ACV) are potent antiviral drugs, but they are ineffective in treating oral-facial herpes infections because they cannot penetrate the skin. The Institute is therefore supporting a clinical study in which a weak electrical current (iontophoresis) improves drug penetration at the site of infection. The results so far have been dramatic in that the healing of active lesions has been accelerated substantially. Other studies supported by NIDR involve developing new antiviral compounds and vehicles for application.

Question: When will such drugs be available for mass use?

Answer: The iontophoresis method to apply antiviral agents to oral herpes will be available to the general public in about 2 or 3 years, if it is judged to be efficacious and safe. This form of

treatment, however, must be carried out by a physician or dentist. As a result, treatment will be more complicated than it would be for a self-applied drug. Studies to develop new drugs and vehicles are underway. It will probably be several years, however, before effective prescription drugs will be available commercially.

Question: To what extent does your research provide residual results useful in the battle against genital herpes?

Answer: In the past, Type I herpes virus was associated with oral infections only, and Type II herpes virus was considered the cause of genital herpes. Today, however, it is not unusual to find Type II virus in oral infections and Type I virus in genital infections. Consequently, our programs on Type I herpes are directly applicable to some cases of genital herpes. Even without cross-infection, NIDR's research on drug treatment reinforces the battle against genital herpes because the same therapy may be effective for both. Furthermore, similarities in viral proteins offer promise that a vaccine against Type I may also be effective against Type II, and vice versa.

FLUORIDES

Question: A major effort has been devoted to developing an anti-caries vaccine, but we know that fluoridation can have a major impact, too. What are you doing to bring the benefits of fluorides to the assistance of more Americans?

Answer: We continue to carry out a variety of educational and promotional activities beyond our previous demonstration projects to encourage communities to adopt the highly cost-effective programs of self-applied fluorides in schools. These efforts have been very successful, with over 13 million school children now involved in such programs. Our professional staff give numerous lectures and seminars to both lay and professional groups on the benefits of fluorides, and provide technical support to the dental disease prevention efforts of the Centers for Disease Control. In addition we are continuing research on improved methods of delivery of topical fluorides, including a slow-release delivery system for intra-oral use.

Question: Would universal fluoridation bring about eradication of caries?

Answer: Universal fluoridation is not possible in the United States because about one-sixth of our population does not have access to public water supplies. Furthermore, even under optimum conditions, water fluoridation prevents only about 60 - 65% of dental caries. Fluoridation continues to be the single most effective way to prevent this disease. The eradication of caries, however, will require the simultaneous use of a variety of preventive methods, many of which are still in the research stage.

Question: To what extent is fluoride incorporated in the food chain -- and what would be the implications of such a development?

Answer: Fluoride is a universally occurring natural element and is found throughout the food chain. Research is continuing to monitor and assess the total fluoride intake of individuals from all sources, including the production, processing, and preperation of

foods. There is no evidence to indicate any adverse health effects from the levels of fluoride routinely present in foods.

FEAR OF DENTAL CARE

Question: Our FY 1983 Committee report made mention of your finding that an estimated 10 percent of the population "avoids needed dental treatment because of excess fear". This strikes us as an area where some hard research work might help bring needed care to a significant fraction of our people. What are you doing about this problem -- and when can we expect results?

Answer: The NIDR currently supports research on the problem of dental treatment avoidance due to fear. Approximately half of this effort is devoted to preventing or reducing fear in children; the remainder is directed at dental fear in adults.

Behavioral interventions that allow the first-time child dental patient to deal with stressful features of dental care are being developed and tested. Results to date indicate that these strategies are remarkably beneficial in reducing dental fear and disruptive behaviors. These techniques now are being modified to apply to a broader range of children.

Studies in adults have demonstrated that, with minimal training, dentists can use systematic desensitization and other behavioral techniques to reduce dental avoidance and fear in patients. In addition, special dental fear clinics have been established recently within several dental schools. Preliminary information from one of these new clinics revealed that many of the patients had extremely poor oral health, apparently as a result of avoiding dental treatment for many years.

The continuation of these studies and the initiation of new projects are expected to lead to clinically useful results within the next 5 years.

RAT MODEL CARIOGENIC POTENTIAL INDEX

Question: In its Strategy Area III to modify the American diet, the NIDR is spending money on a rat model to develop a Cariogenic Potential Index (CPI). As the Subcommittee understands it, in this rat model rats are fed the same finely ground food substance 17 separate times a day. They do not receive any other food substance through their mouths, but instead their stomachs are hooked to tubes through which other nutrients are pumped into them. If the rats survive this procedure, they are decapitated and their teeth are examined for dental decay. It would seem that all of this procedure has a purpose only if as a matter of anatomy, physiology and dentistry what happens to the dental condition of rats could be expected to have a similar effect in humans.

Does the composition of saliva play an important role in the process of developing or resisting caries?

Answer: It is uncertain whether specific constituents of saliva influence the onset of caries, as no significant differences other than flow rate have yet been found in saliva of caries-susceptible

and caries-resistant individuals. Such parameters as salivary buffer capacity, secretory immunoglobulins, lactoferrin, lactoperoxidase and lysozyme are being investigated as possible protective mechanisms against caries, though their role is not yet established.

Question: Does salivary flow play an important role in cleansing food from the mouth? If so, does this have an effect on the caries process?

Answer: Salivary flow influences food clearance time. Prolonged clearance times of acidogenic foods is believed to increase cariogenicity.

Question: What are the differences in the composition of rat saliva and human saliva?

Answer: Rat and human saliva, particularly that from the parotid and sublingual glands, are remarkably similar in composition. Both are hypotonic and have comparable inorganic composition. While the organic composition of rat saliva is not as well characterized as that of man, there is considerable evidence from gel electrophoresis profiles that they are extremely similar. Indeed mucins from rat saliva are virtually indentical to those in human saliva. Rat saliva possesses the same specific and innate host defense factors as human saliva with the exception that rat saliva contains transferrin instead of lactoferrin. Importantly, the regulatory mechanisms of salivary gland function in man and rat are comparable.

Question: What are the differences in the salivary flow capabilities of rats and humans?

Answer: When considered on a volume of saliva per gland weight or on a volume per body weight basis the flow rates of rat and human saliva are comparable.

Question: What are the differences in the tooth structures of rats and humans?

Answer: The major differences in tooth structure between rats and humans are found on the biting surfaces. In humans, these surfaces typically contain narrow pits and fissures which are highly retentive for bacteria and food particles. In rats, the analogous areas are wide grooves, which are more easily cleared of food, assuming (as in our experiments) that the particle size of the food is small enough to prevent impaction.

Question: Last year the NIDR assured this Subcommittee in writing that its testing methods involved "measurement of caries in laboratory animals under normal eating conditions." Are the procedures of this rat model "normal eating conditions"?

Answer: "Normal eating conditions" referred to the fact that, in our experimental model, snack foods are fed as snacks (that is, multiple times each day). Unlike the situation in humans, the number and frequency of snack meals is carefully controlled. As with all biologic models of human disease processes, the rat-caries model differs from the human in many respects, though results from rat experiments with fluorides and antimicrobials, for example, have been highly predictive of results obtained in subsequent human trials. However, studies to verify the cariogenicity of specific foods cannot

ethically be carried out in humans. Therefore we avoid the use of the term "cariogenic" to describe foods tested in rats, and refer instead to their "cariogenic potential" relative to pure sucrose.

Question: Can the eating of foods in combinations and in sequences change their cariogenic potential?

Answer: Preliminary research in rats suggests that the sequence of eating different foods influences their cariogenic potential. For example, the cariogenic potential of a meal of a sugar-containing food was reduced when a meal of cheese was fed immediately after. Whether this effect is due to stimulation of salivary flow or to some constituent of the cheese is still being studied.

Question: The Food and Drug Administration and the Department of Agriculture appear to be funding similar rat tests. Why is the NIDR duplicating these expenditures by other agencies?

Answer: Research with rats on the cariogenic potential of foods at the NIDR began long before similar research by the American Dental Association. The latter is supported in part by the FDA and the USDA. Some of the methods developed by the NIDR are in use in the ADA studies. We think it highly desirable that independent laboratories work on these questions, and many are doing so, both in the U.S. and in Europe.

CARIES REDUCTION

Question: In the FY 1982 Annual Report of the National Caries Program, the NIDR states that "the decrease in dental caries among children is an encouraging observation, which attests to the success of recent research on caries prevention." What "recent research" is the NIDR talking about?

Answer: The "recent research" referred to in the FY 1982 Annual Report and believed to be a major factor in the recent decline in caries in children is primarily research with fluorides. This includes our studies and promotional efforts with school water fluoridation and self-applied fluoride mouthrinses and dietary supplements for use in schools.

Question: Is this fluoride research or was it research on changing the American diet?

Answer: The research was primarily with fluorides. Research on alternative sweeteners, for example, has only recently begun to result in the introduction of new sweeteners into the food chain; the effect of these products on caries prevalence would therefore not have been reflected in recent epidemiologic surveys.

Question: What specific research projects in Strategy Area III for modifying the American diet have brought about the decrease in dental caries among children?

Answer: We do not attribute changes seen thus far in caries prevalence to be the result of research on the modification of causative factors in the diet. Unlike the situation in several European countries, only a small number of non-cariogenic snack foods are available to the American consumer.

NIDR FOREIGN EXPENDITURES

Question: It has come to the subcommittee's attention, that the NIDR is spending research money outside the United States for schools in foreign countries to conduct dental research. In recent years, NIDR budget dollars have been spent in Canada, Australia, Sweden, France and Israel, at a time when American institutions of higher learning are suffering from severe cutbacks in their budgets for education and research.

Why is the NIDR spending appropriated funds outside the United States?

Answer: The NIH and the NIDR have had a long-standing policy of international cooperation in the biomedical research field. The basis of this policy is the belief that the most efficient way to solve mankind's health problems is to foster free exchange of information and maximum cooperation among scientists throughout the world. This policy has not only accelerated the solution of many health problems, but it has enabled this country to develop a strong and vigorous biomedical research capability that is unique in history. In the dental sciences, the revolutionary advances that have been made during the last 30 years are to a large extent a result of the unrestricted flow of information across continents and the increased mobility of researchers, educators and clinicians.

During the last four decades the United States has had bilateral international cooperative agreements with more than 40 different countries; moreover, there have been many instituiton-institution agreements and a plethora of informal arrangements between investigators and laboratory teams. Under these arrangements foreign scientists have come to this country, where they have contributed directly to the U.S. research effort. While gaining valuable scientific experience themselves, scientists have made the same type of contributions abroad and enjoyed the same benefits. The fruits of such efforts have always become available for world-wide use. It seems clear that science knows no borders, national, geographic, ethnic or racial; and that information is to be sought wherever in the world that answers and solutions might be found. Accordingly, the NIDR has directly supported a modest number of selective studies of high quality that offer unique opportunities for dental research. In every instance, the expected benefit is new information which may be helpful in improving the oral health of our citizens.

Question: Don't we have dental research facilities and universities in this country every bit as capable of conducting dental research as schools in other countries around the world?

Answer: Yes, we do have dental research facilities and universities with capabilities equal in quality to those in other countries. However, these facilities in the United States are not always coupled with the appropriate research manpower and study populations required to respond to all important scientific questions. In such instances, the Institute looks abroad for the particular combination of research opportunities and appropriate talent to address a unique problem, which may be impossible to address within the U.S.

Question: Why don't those foreign schools get their dental research money from their own governments?

Answer: Foreign schools do receive the major portion of their dental research funds from their own governments. NIDR support is typically a rare occurrence at any specific foreign institution.

Question: Why should the U.S. pick up the cost of underwriting dental experiments in other countries when universities here in our own country are crying out for funding help from the Federal government?

Answer: More than 99% of the NIDR research budget is distributed to universities and research institutions within the United States with only a relatively minute portion of its research budget to underwrite projects abroad. Because certain oral diseases manifest themselves in unique ways in other parts of the world, they may have to be studied in their natural environment to obtain information potentially useful for the disease as it is manifest in this country. Unique specialized research manpower may exist abroad which can be mobilized to address oral health problems of consequence in this country.

Question: Please furnish the subcommittee with a complete list of all dental research projects on which the NIDR has spent money since 1979 outside the United States, as well as a complete list of all the dental research projects on which the NIDR proposes to spend money outside the United States in this Fiscal Year and in the coming Fiscal Year. For each of these research projects, please let us know whether feasible research alternatives are available here in the United States.

Answer: Foreign Research Expenditures - Fiscal Years 1979-1984

Projects	Country	FY79	FY80	FY81	FY82	FY83 Est.	FY84 Est.
R01 DE04174	Australia	53,661	59,732	83,196	73,916	81,298	—
Variations in the Surface Structures of Oral Bacteria							
R01 DE04175	Australia	58,242	65,031	105,945	72,365	77,380	—
Variations in the Surface Structures of Oral Bacteria							
R01 DE04786	Canada	50,313	44,485	70,359	61,098	68,440	—
Dental and Orofacial Pain: Brain Stem Mechanisms							
R01 DE04890	Sweden	74,636	54,436	54,436	66,741	67,445	70,255
Systematic Plaque Control - Healing Following Periodontal Surgery							
R01 DE05404	Canada	24,686	35,426	13,833	32,485	24,047	25,791
Dental Pain: Studies of Trigeminal Nucleus Caudalis							
R23 DE05424	Canada	25,000	25,000	25,000	—	—	—
Quantitative Studies of Lysosomes in the Amelogenesis							
R23 DE05453	Israel	—	—	13,528	—	—	—
Dynamics of Matrix Vesicle Activity in Socket Healing							
R01 DE05690	Canada	—	—	82,500	78,086	88,173	—
Localization of the Procollagens in Dental Tissues							
R01 DE05780	Israel	—	—	—	49,379	47,900	50,457
Development and Mineralization of Enamel in Teeth							

Projects	Country	FY79	FY80	FY81	FY82	FY83 Est.	FY84 Est.
R01 DE04257 Migration and Differentiation of Neural Crest Cells	France	--	20,500	28,000	26,880	--	--
R01 DE05375 The Surface Composition of Biological Apatites	Australia	--	--	26,063	23,212	--	--

All of the studies curreatly being supported are timely projects which are unique in some way, so that feasible alternatives for accomplishing that particular research are not available in the U.S. at this time. For example, in the two projects in Australia, highly innovative investigators are using a special system thay have devised to study the adherence of bacteria to teeth and to other tissues. This subject is of critical importance to the study of dental caries and other infectious diseases. In other instances, the investigators are working in unique areas, using special facilities, resources or study populations.

Foreign projects supported by NIDR for FY 1979 and subsequent years have constituted from 0.42% to 0.63% of the NIDR budget. It should be pointed out that each foreign grant awarded must not only undergo rigorous peer review for scientific merit, but must offer a unique opportunity not available in the United States. Such a project must also be approved with a priority score in the top half of all grant applications being reviewed at that time. Foreign projects are awarded for no more than 3 years and no indirect costs are paid.

CONSUMER ACCEPTANCE OF ARTIFICIAL SWEETENERS

Question: Can NIDR show us any sales history or market research which indicates that if artifically-sugared, non-cariogenic products were available, the American public would buy those products on the basis that they were not cariogenic?

Answer: We have no access to manufacturers' sales histories or market research results. Products containing saccharin and, when they were available, cyclamates, have evidently been readily accepted by consumers. According to USDA data, consumption of saccharin has increased more than 300 percent since 1960. Market research on a new sweetener, aspartame, has been conducted in several areas of the country and has been followed by large-scale introduction of aspartame-sweetened products, implying high potential for consumer acceptance. A chewing gum sweetened with sorbitol (a polyol) is also reported to have a large segment of that market. No doubt many consumers purchase foods containing non-caloric sweeteners for dietary reasons though this will, of course, also confer oral health benefits.

Questions Submitted by Senator Mark Andrews

SUGAR AND CARIES

Question: I notice in this year's budget proposal for the NIDR that it again is seeking funds to modify the American diet, with particular attention to sugared foods. What I read in the press about research findings on the cause of caries seems to say that

sugar may not be the villain that we have all been led to believe over the years. There have been articles in leading newspapers, as well as in scholarly journals, which indicate that not just sugar, but in fact any foods that contain "fermentable carbohydrates," can cause dental caries.

In one recent news article quoting Dr. Stephen Moss, Chairman of the Department of Pedodontics at the New York University Dental Center, the American Dental Association reports that simply reducing total sucrose intake may not prevent dental caries. Dr. Moss agreed:

> "As sure as I know night follows day, I always believed that refined sweets and gooey candies were the forbidden foods for healthy teeth. But for the last few years, ongoing dental research has shown a new focus on the diet-cavity connection. New findings from scientific centers worldwide are too consistent to keep on believing that sweets alone are what play havoc with our teeth. Since starches are broken down to sugars before they leave the mouth, we now look at all carbohydrate foods -- those with simple sugars such as raisins, candy, jellies, bananas and honey; as well as those with complex sugars (starches), like breads, cereals and potatoes -- as being potentially cariogenic."

Dr. Moss explained:

> "Bacteria in the mouth can't read labels. We need to switch the focus from what and how much carbohydrate we eat to how often, how frequently, we eat them during the course of the day."

Does NIDR still believe that sugar is the villain in the cause of caries, and that removal of sugar from the American diet would mean the end of caries?

Answer: Although any bacterially fermentable substrate is capable of causing some dental caries, research has consistently shown that sugars are by far the most cariogenic substances in the American diet. In an experiment in Finland, for example, a near total reduction in caries resulted when all added sugars in the diet were replaced by xylitol. Elimination of all sugars from the normal diet, however, is both impossible and unnecessary. It is the frequency of eating sugars, rather than the amount eaten, that is critical in caries causation. Therefore, reducing between-meal eating of sugar-sweetened snacks would probably achieve further major reductions in the incidence of caries.

ARTIFICIAL SWEETENERS

Question: How many years have you been trying to develop non-cariogenic artifical sweeteners to replace sugar in processed foods?

Answer: We have been involved in research on non-cariogenic sweeteners for about 12 years. It has been a very minor, but essential, component of our overall program on caries prevention.

Question: Has NIDR itself successfully developed any non-cariogenic artifical sweeteners?

Answer: The NIDR has conducted or supported research on the development of many non-cariogenic sweeteners, several of which are being considered for marketing by industry. Our role has been to assist and to encourage the basic research necessary to identify and characterize such compounds, and to assess their effect on the metabolism of dental plaque and on dental caries. We have, for example, conducted cariogenicity testing of aspartame, an artifical sweetener recently approved by FDA.

Question: Haven't most privately developed artificial sweeteners been plagued by FDA concerns over their safety?

Answer: Any food additives, including new sweeteners, must undergo intensive toxicology testing, required by the Food, Drug and Cosmetic Act, before they are approved for human use. Concern about the safety of sweeteners has been no different than that directed to any new drug or food additive proposed for marketing.

Question: Why doesn't NIDR leave it to the private sector to experiment with artifical sweeteners? It would seem that if new artificial sweeteners were likely to obtain FDA safety approval and consumer acceptance, then the private sector would be busily searching for them as a way to sell new products.

Answer: When the NIDR began supporting basic research on sweeteners, there was very little commercial activity in this area. Since then, industrial interest has greatly increased and, accordingly, we have reduced our involvement in this research. We understand that intensive research on the development of artificial sweeteners is now underway in the private sector.

CARIOGENICITY

Question: The Annual Report of the Associate Director of NIDR, in discussing this past year's National Caries Program research findings, indicates that the cariogenicity of certain foods doesn't always follow what conventional wisdom would predict. For example, the report states that some potato chips, despite their low sugar content, are highly cariogenic. On the other hand, a caramel candy that was tested, despite its stickiness and its tendency to stay in the mouth longer, is less cariogenic than sucrose itself.

In view of these and other new findings we have been reading about in the press, do you still intend to try to replace the sugar in processed foods with a non-cariogenic artificial sweetener, particularly now that we know that natural foods like apples, carrots, pineapple, potatoes, figs, raisins and grain foods can cause caries to the same extent as sugared processed foods? And that some unsugared processed foods like potato chips, crackers, bread and cereals can be just as cariogenic as sugared processed foods?

Answer: Naturally sweet foods such as raisins, figs and apples have high sugar content and are presumably cariogenic if frequently eaten. Some processed foods, such as the potato chips tested in our laboratory, and some crackers, cereal products, condiments, etc. often have an unexpectedly high content of sugars that are added

during processing. It is not surprising that such foods prove to have high potential for causing dental caries. Processed foods that do not contain sugars have been consistently less cariogenic in both animal and human experiments. In addition to sugar content, other constituents of a food, as well as its physical properties, also influence its potential to cause cavities.

Question: How do you intend to replace the sugar in milk, fruits and vegatables with artificial sweeteners?

Answer: We do not, or course, advocate the replacement of sugars that occur naturally in foods. Our goal in caries prevention is to give consumers the opportunity to choose palatable, sweet, but non-cariogenic alternatives to processed, sweet snack foods with high cavity-causing potential. I should add, however, that we strongly advise the public to avoid frequent ingestion of unprocessed foods--raisins, for example--that have a high sugar content.

PUBLIC EDUCATION

Question: Getting back to flouridation, and the remarkable results in reducing caries that we have seen with its use, I notice in your budget proposal that you express concern that money available for pamphlets and other educational materials has been reduced.

Is it correct to assume that this has reduced the amount of educational materials available to the public on the remarkable effects of fluoride in preventing caries?

Answer: We feel that our budget can still support public education and promotion activities on the benefits of fluoride. In fact, we are now conducting an aggressive and, we think, successful campaign to produce and distribute handbooks, brochures and audio-visual materials to inform the public and professionals about fluorides. We are particularly pleased that the pharmaceutical industry is collaborating with us on this effort. School-based self-applied fluoride programs continue to expand, and our staff is investing significant time and energy to provide appropriate information and assistance. We are quite happy with our progress to date; however, we must broaden these educational activities to extend the benefits of fluoride even further.

CARIES PREVENTION

Question: I have taken note of widespread publication within the last year of the NIDR's current opinion that the extensive use of fluorides in the United States has caused very substantial reduction in tooth decay among children. However, I am disturbed by the fact that the availability of fluoride seems inadequate for many American children. The NIDR itself says that 35 million American school children do not have the benefits of self-applied school-based fluoride programs, and the NIDR is unhappy about the very limited resources available to it to improve this situation.

However, at the same time as the NIDR talks about being short of money for improving fluoride programs for school children, it nonetheless comes back to the Subcommittee requesting that we give it another year of funding for its program to modify the American diet by substituting synthetic sweeteners for natural sugars.

If the NIDR tells us that fluoride is causing dramatic reductions in children's dental decay, why not stop spending the NIDR budget on efforts to eliminate natural sugars and instead spend those same budget dollars on research projects and practical programs to educate the public and to increase the availability of fluoride to more American children?

Answer: We certainly intend to continue our intensive efforts to bring these preventive programs to more people. These efforts include our research on improved methods of delivering fluorides, as well as education and promotion of methods already available. However, everything we know about the cause of dental caries suggests that maximum prevention of this disease will best be achieved by simultaneous efforts not only to improve the resistance of teeth with fluorides, but also to reduce the causative roles of bacterial plaque and dietary practices. Our strategy for caries prevention research includes all of these efforts.

Question: If fluoride is so very effective in reducing caries, aren't there any fluoride projects on which the NIDR could make better use of the money that it is now spending researching such artificial sweeteners as Japanese hydrangea and sweet-tasting Chinese flowers?

Answer: Because fluoride plays a vital role in reducing cavities, it has long commanded a major share of the caries research budget. Fluoride, however, is not 100 percent effective, and it is essential to try to reduce the continued risks imposed by dietary causative agents. Our goal, therefore, is to help insure that the public has a choice in the marketplace between the traditional sweet snack foods and those that do not contribute to dental caries. This a relatively small, but essential, part of our overall research strategy for prevention which we feel is well balanced among the research goals of improving tooth resistance, controlling cariogenic bacteria and reducing decay-causing dietary factors.

DIET MODIFICATION

Question: If fluoridation is cost-effective and of dramatic benefit in reducing dental decay in the United States, what objections would the NIDR have to allocating the same budget dollars to increasing the resistance of the teeth through fluoridation that it now instead wants to spend year after year on diet modification? Why not just eliminate all of this diet modification research that is targeted at how persuading the American people to stop eating natural sugars and to substitute synthetic chemicals of questionable safety?

Answer: Our judgement is that a simultaneous effort to find cost-effective ways to control all factors involved in causation of caries is the most prudent scientific strategy to eventually control this disease. To ignore any one factor, such as diet, would be to dismiss compelling evidence from decades of research on the causes of caries. It is not, however, our goal to change America's diet. This decision can only be made by the consumer. Rather, it is our goal to provide the public with information on how caries can be prevented, and to help insure that consumers have the opportunity to make rational choices, with minimal inconvenience, about oral health. This has been our consistent philosophy in all of our research toward the prevention of dental caries.

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NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

STATEMENT OF DR. LESTER SALANS, DIRECTOR

ACCOMPANIED BY:

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DR. JAMES B. WYNGAARDEN, DIRECTOR, NIH
NORMAN D. MANSFIELD, DIRECTOR, DIVISION OF FINANCIAL MANAGEMENT, NIH
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BUDGET REQUEST

Senator WEICKER. Next, we will hear from the National Institute of Arthritis, Diabetes and Digestive and Kidney Diseases which conducts research on a number of debilitating and costly diseases.

The Institute is requesting $426.3 million for fiscal 1984. This is $5.7 million more than was requested in the January budget and $14 million above the fiscal 1983 level.

Here to testify on behalf of the Institute's budget is Dr. Lester Salans, the Director.

We welcome you and your staff. And please proceed.

Dr. SALANS. Thank you, Mr. Chairman.

Let me please first introduce my colleague on my left, Mr. Earl Laurence, who is Executive Officer of our Institute.

I am very pleased to have the opportunity this morning to report on the significant and in some cases remarkable progress——

Senator WEICKER. I apologize. I have been informed I mispronounced your name. It is Sa-lans; is that right?

Dr. SALANS. That's fine; either way.

Senator WEICKER. Which way is it?

Dr. SALANS. Sa-lans is the way I pronounce it.

Senator WEICKER. I will tell you, nobody pronounces my name right, and I don't like it. So I feel that is the least due to either you or myself. And I apologize for the mispronunciation.

Dr. SALANS. Thank you.

I was saying that I think the research that this Institute supports and conducts has made some very significant and remarkable progress during recent years. We are responsible for research on some of the most widespread and serious diseases affecting the health of our citizens, diseases which are estimated to cost the economy of this country more than $1 billion every year.

This progress in large part, Mr. Chairman, is the result of the application of new knowledge from basic research to the study of specific diseases, often with very dramatic results.

In addition, I think it is fair to say that clinical investigation is increasingly becoming more sophisticated. I would like to cite to you a few examples of our progress.

Scientists in our Institute and in the Allergy and Infectious Diseases Institute have discovered the specific bacteria that causes the disease Lyme arthritis. This discovery has enabled physicians to control this disease with penicillin.

Great strides are also being made in understanding the underlying basis of several other types of arthritis. And these studies are promoting the development of new methods to prevent and treat many other forms of this devastating group of diseases.

In diabetes, basic research has permitted us to better identify the underlying causes of the insulin-dependent form of the disease and to identify those individuals who are at increased risk for developing this disease. As a result, several experts predict that it will be possible to prevent insulin-dependent diabetes in the foreseeable future.

And for the first time in more than 50 years, we are able to begin a clinical trial on the devastating complications of diabetes with potential savings of billions of dollars each year.

In the area of digestive diseases, basic research has led to new, more effective, treatments of peptic ulcer disease. As you may well know, the drug cimetidine has considerably reduced health care expenditures for an estimated 4 million Americans who suffer from peptic ulcers.

Research has also begun to show how viral hepatitis B, which affects at least 5 percent of the world population, leads to liver cancer, the leading cause of internal cancer in the world. The recent development of the hepatitis B virus vaccine may prevent these two very serious diseases.

Finally, Mr. Chairman, kidney researchers have developed a comprehensive approach to the evaluation and treatment of kidney stones which costs an estimated $400 million annually. Research has made it possible to prevent recurrence of up to 80 percent of kidney stones in patients who are habitual stone formers.

These, Mr. Chairman, are but a few of the examples which illustrate, I think, the strength and productivity of NIADDK research.

The 1980's, as you have heard, are a period of vast scientific opportunity and unprecedented research momentum. And we are committed to vigorously pursuing our mission in this regard.

Mr. Chairman, I would be pleased to answer any questions that you may have.

COMPETING GRANTS

Senator WEICKER. The problem with this picture that you all present as you come up here on behalf of each one of your Institutes, is that you obviously have some good news to tell, but, as has been correctly

pointed out by Dr. Wyngaarden, the seeds of much of the good news that you are telling were planted decades ago and the funding provided decades ago.

And my concerns with this budget are that your successors decades hence will have similar good news.

Maybe you would like to get into the matter of the competing grants, first of all giving the numbers revision as between the original budget and what you will now get in terms of numbers. And then, maybe you might just continue to discuss the matter of funding of the grants and how that affects your Institute.

Dr. SALANS. Mr. Chairman, the number of competing grants the NIADDK was to award under the original President's budget was 523. We now expect to fund 714 competing grants, an increase of 191 competing grants.

Senator WEICKER. How do you see the moneys in proportion to the greater number of things?

Dr. SALANS. Our ability to fund this number of competing grants is the result of a shift of dollars from other mechanisms primarily, but not solely, from research centers, plus reductions in direct and indirect costs in the support of research grants that we award

These shifts of funds to the research project mechanism permit us to reach our share of the NIH stabilization level of 5,000 competing grants for 1984.

RESEARCH CENTERS CUT

Senator WEICKER. In order to achieve that, it is my understanding from the NIH memorandum that funding would be eliminated for Michigan—I am talking about the Multipurpose Arthritis Centers: Michigan University; Brigham and Womens Hospital, Boston; Arizona Medical; Washington University, St. Louis; Stanford; Boston University; Alabama University; University of California, San Francisco; University of Connecticut; State University of New York; and University of Missouri. There is also an Arthritis Core Center at Brigham and Womens Hospital in Boston; a Diabetes-Endocrinology Research Center at the University of Iowa; a Diabetes Research and Training Center at Vanderbilt; an Endocrinology Research Center at University Hospital, Boston; and a Clinical Nutrition Research Unit at Vanderbilt.

Correct?

Dr. SALANS. That's correct.

Senator WEICKER. How does that affect the total objective?

Dr. SALANS. Well, I think others who have spoken before me have given you an idea of how it affects their Institute. I think we are in a similar position. Clearly, we consider our centers program to be a valuable and important component of the overall effort to combat the diseases for which we are responsible.

But at this time, the Department and NIH has determined that our highest priority is in the area of investigator initiated research project grants.

It is not that centers are unimportant or that they have a low priority, but during this period of fiscal constraint, priorities amongst the various mechanisms for supporting research have to be made. It has been determined that painful as it may be, it was necessary to shift funds from research centers so that we could support an adequate number of investigators through the mechanism of highest priority, investigator-initiated research grants.

BUDGET DECISION PROCESS

Senator WEICKER. Let me ask a question I have not asked the others. I would if they are all here.

I want to know whether or not your advice was sought, prior to the raising of the figure to 5,000, or, in other words, were you notified after the fact as to what was going to happen?

I would like to know whether your advice was sought in terms of this whole matter of competing grants, the official numbers, how that would impact in the sense of a reduction of the centers, et cetera. Was that advice sought before or after the fact?

Dr. SALANS. I think it is fair to say that the NIH Directors met and discussed this issue at great length throughout the entire course of this decisionmaking process. We weighed all aspects of this dilemma and came to the conclusion that the policy which has been articulated by each of us here this morning, and as reflected in this budget, is, under the present economic conditions, the wisest approach.

I would add, Mr. Chairman, that in our Institute, we have had the opportunity to go around the country, hold formal meetings with our grantees and discuss this policy at great length.

I think that the general feeling of our grantees is that while we are facing what is hoped to be a relatively short-term financial crunch, the decision to maintain the maximum number of investigators in the system doing research through research project grants makes sense. The hope is that when economic recovery comes, enough people will still be doing investigator initiated research, and at that time, we can once again strengthen the other mechanisms for supporting research such as centers.

Senator WEICKER. I think you are on far safer ground, doctor, if you stay on the matter of the moneys allocated within your agency and NIH as a whole rather than getting into philosophical discussion of economic recovery and priorities.

Do you ever attend any functions with the admirals and generals these days? Have you ever asked them if they have any choices to make?

Dr. SALANS. I have not had that opportunity. I am not sure I am looking forward to it.

Senator WEICKER. Well, they don't have any choices to make. They get what they ask for.

My question again is, now coming back at your response to me, I would gather, then, it was at your request and the other Directors of

the ot · Institutes that the number of competing grants was raised to 5,000, ..id also at your request that the research centers be reduced; is that right?

That was my question, whether your advice came after the fact, after the 5,000 level was decided upon, or indeed was it at your advice that you went to 3,376, or whatever it was, up to 5,000 with the resultant changes that had to be made.

Dr. SALANS. I think my answer to that question—I'm sorry that it wasn't clear—was that we were consulted in the decisionmaking process which led to the final budget that——

Senator WEICKER. Again, my question to you is: Were you asked to produce the changed budget you need to go from 3,300 to 5,000 or consulted when the level was established at 5,000? At what point, in other words, were you consulted?

Dr. SALANS. When it became clear that a choice had to be made as to how a limited number of dollars were going to be spread, we discussed whether those dollars should be put primarily into research projects to restore the 5,000 competing grants or whether the dollars ought to be left in other mechanisms such as centers, training, et cetera.

We actively participated in the decision that was made.

Senator WEICKER. Is that answer sufficient for all the various Institutes?

Dr. Lenfant?

Dr. LENFANT. Mr. Chairman, we did participate in the process, and we were presented a number of alternatives. And I think, as Dr. Salans, that the support of the research was, considering the situation, the best alternative that we had to follow at that time.

But I would like to add to what has been said that concerns those of us who have a balanced program—it encompasses more than the investigator initiated grants. The curtailment of all activities may be a thing which would be difficult to conceive this year and in the following years.

Senator WEICKER. Dr. Löe?

Dr. LÖE. I don't think I have anything more to add. It is basically the same from all points of view.

If you ask me what is most important to my Institute, it is the investigator initiated grants that have the highest priority.

Senator WEICKER. In other words, you are one of those who recommended the competing grants go from 3,200 to 5,000 at the expense of other activities?

Dr. LÖE. I don't think it happened that way.

Senator WEICKER. I don't think it did either, doctor.

Thank you.

Dr. DeVita?

Dr. DEVITA. Well, Mr. Chairman, Dr. Wyngaarden is well aware of all our positions on these various issues. As I recall it, however, the decision was made—5,000 grants—and we responded with long discussions as to how we might go about doing it.

Senator WEICKER. Thank you, doctor.

MYCOPLASMA AND RHEUMATOID ARTHRITIS

In the fiscal 1983 report, the committee asked you, Dr. Salans, to look into mycoplasma-related causes of rheumatoid arthritis. We also asked that you examine relevant clinical data and take into account the possible importance of duration of treatment as a factor.

Where do you stand on this inquiry, and what are your findings? And don't you have data more recent than the 1971 clinical trial you refer to in your report?

Dr. SALANS. Mr. Chairman, we will be submitting that report to the Senate shortly. We are currently preparing the report on mycoplasma and rheumatoid arthritis.

Let me make a brief comment or two. That submission will be based on a thorough review of the modern literature and a review of what NIH and other agencies may be supporting in the area of mycoplasma research at this point in time. I think it is fair to say that the mycoplasma theory has not been established yet; there are some who feel that there is evidence that mycoplasma infection may play a role in some forms of arthritis, and many other researchers do not feel that there is evidence to support this theory.

Definitive data are not yet available and additional research is going to be required. Our report will identify for you the current status of our knowledge and the opportunities that exist in this area.

CYCLOSPORIN

Senator WEICKER. We understand that the immuno-suppressant cyclosporin A can contribute substantially to the success of kidney transplants.

We understand cyclosporin A has been successfully used in transplants in Canada. To what extent is this an important development in the field?

Dr. SALANS. I think that cyclosporin A may be a critically important advance in immuno-suppressive treatment. It is increasingly being utilized for transplantation, not only of the kidney, but also of other organs, especially the liver and more recently the pancreas. The experience has been good.

It appears to be a much more effective immuno-suppressive agent than any other form of immuno-suppression being used at this time. It is associated with much less infection, and in the area of kidney transplantation, it is associated with considerably less kidney rejection and, therefore, an increased survival of kidney transplants.

At the same time, it needs to be stressed that our experience with this drug has been sufficiently limited to render a note of caution. We do not know whether there may be some untoward effects associated with the use of this agent. Some potentially serious side effects have been reported in association with the use of cyclosporin A, but it is premature to draw definitive conclusions. But on the whole, I think it is a potentially important new agent.

PREPARED STATEMENT AND SUBMITTED QUESTIONS

Senator WEICKER. I have further questions that require response for the record. Your statement will also be included.

And I thank you, Dr. Salans.

[The information follows:]

Statement of Dr. Lester B. Salans

The National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) supports and conducts research on some of the most serious diseases affecting the health of our nation's citizens. The diseases for which the Institute bears research responsibility are among the most common, debilitating, and costly in the United States. Over 37 million Americans suffer from different forms of arthritis and related musculoskeletal diseases. Approximately 11 million adults and children have diabetes and approximately 300 thousand die annually from the disease and its complications. Chronic digestive disorders affect 20 million Americans. Digestive diseases cause about 200 thousand deaths annually and hospitalize more people than any other group of diseases. Kidney disease claims the lives of over 50 thousand Americans each year. In 1982, over 70 thousand end stage renal disease patients were kept alive by dialysis or transplantation under the Medicare program at a cost of about $1.8 billion. The collective economic burden of the diseases addressed by this Institute exceeds $100 billion annually.

Program Interrelationship

To conquer these diseases, the Institute sustains a far-ranging, multidisciplinary research program characterized by excellence, innovation, and productivity. A strong foundation of basic research is complemented by vigorous clinical research on the diseases of internal medicine and related skin, bone, and urological diseases.

Strong interrelationships exist among different Institute programs which depend on common scientific threads like metabolism, endocrinology, immunology, and molecular genetics. Enormous advances in these areas are now being successfully applied to the study of all the diseases within the Institute's research mission. In immunology, research on the new immunosuppressive drug Cyclosporin A holds great promise for improving the success of both kidney and liver transplants. Similarly, a blood filtering technique called apheresis is being studied in clinical trials in both rheumatoid arthritis and in the kidney disease associated with systemic lupus erythematosus. Our programs clearly benefit from close and productive interaction.

Arthritis, Musculoskeletal and Skin Diseases

Arthritis research is a cornerstone of this Institute and an area of intense scientific activity and progress. It is now clear that arthritis is not a single disease, but rather a group of perhaps 100 or more disorders with many different causes, including genetic, immunologic, inflammatory, and infectious factors. We are gaining a better understanding of the vital role of the body's immune defense system in rheumatoid arthritis and other rheumatic diseases. In patients with rheumatoid arthritis, a specific defect has been found in cells of the immunologic system that normally suppress the body's ability to produce antibodies against the virus associated with infectious mononucleosis. This finding provides an important new insight into the immunologic basis of rheumatoid arthritis and may lead to development of specific immunologic treatments. New knowledge about the role of various mediators of inflammation is also increasing our understanding of the inflammatory processes involved in rheumatoid arthritis.

Another form of arthritis, systemic lupus erythematosus, is a connective tissue disease in which the body's immune system attacks its own tissues. Researchers have made significant advances in understanding the nature of these abnormal autoimmune processes and of the roles of hormones, viruses, and genetic factors in the etiology of this disease.

Research on the cause of osteoarthritis includes promising biochemical and metabolic investigations. Recently, new knowledge has been gained concerning development of the earliest lesions seen in osteoarthritis.

Advances continue to be made in the refinement of artificial joints to restore mobility and relieve pain in severe arthritis. An NIADDK consensus conference noted that 90 percent of total hip joint replacements are successful as long as ten years after surgery. The success rates for total knee replacements and other joint replacement surgery continue to improve.

Special proteins that regulate and promote bone growth have been isolated from animal and human bones. These discoveries are significant, since the ability to control or replace specific bone factors may lead to dramatically improved therapies for a wide range of bone diseases.

The treatment of skin diseases is being revolutionized by research on newly synthesized derivatives of vitamin A, called retinoids. Retinoids are effective in treating severe scarring acne, and now show promise in scaling disorders of the skin, such as psoriasis and ichthyosis. Researchers have also identified a drug, diphenylhydantoin, that is helpful in treating the skin blisters of children with epidermolysis bullosa.

Diabetes, Endocrinology and Metabolic Diseases

Remarkable advances over a broad spectrum of diabetes research are giving us potent weapons to combat one of the most serious public health problems in the U.S. today. A promising approach to improved treatment of insulin-dependent diabetes involves transplanting normal insulin-producing pancreatic cells into diabetics who have lost the capacity to produce insulin. A strong and highly productive research effort, in experimental animals, is devoted to this approach.

Researchers are identifying genetic and immunologic defects that may indicate that an individual is susceptible to, at high risk for developing, or in the earliest stages of diabetes. Investigators have found variations in the area surrounding the insulin gene which appear to correlate with differences in susceptibility to developing noninsulin-dependent diabetes. If these or other specific abnormalities can be confirmed to play a causative role in diabetes, it may be possible to modify the expression of the abnormal genes and prevent certain types of diabetes. In related research, an immune abnormality was uncovered in recently diagnosed insulin-dependent diabetics. This discovery may enable us to develop ways to prevent the body's immune system from destroying pancreatic cells needed for insulin production. Pursuing these and other important findings is a major priority of this Institute.

Intensive study in endocrinology and metabolic diseases continues to yield new insights into the regulation of various body

functions and specialized organs, tissues, and cells. Researchers recently have identified a new hormone which controls the secretion of growth hormone from the pituitary gland and may therefore prove useful in ameliorating growth disorders and short stature in some children. Recombinant DNA techniques have enabled the synthesis of human growth hormone, somatostatin, and insulin. Synthetic human insulin recently has been approved by FDA for commercial marketing and synthetic human growth hormone is being tested in clinical trials. Intramural scientists of this Institute have devised an experimental technique for replacing defective enzymes in certain disabling and fatal inherited metabolic disorders such as the Hurler and Hunter syndromes. If this approach proves feasible, new enzymes could be given to patients in much the same way as insulin is given to diabetics.

A vigorous research effort is being pursued in cystic fibrosis (CF), the most common fatal genetic disease of Caucasian children. A cardinal disease symptom believed linked to the cause of CF is saltiness of sweat secreted by patients. Recent research has shown that this reflects an impairment in the sweat gland's ability to reabsorb salt due to a diminished ability to transport chloride. This new knowledge will help accelerate the search for the underlying metabolic defect in this disease. In this regard, I am pleased to report that the Institute is funding a major, sophisticated cystic fibrosis research center at Case Western Reserve University in Fiscal Year 1983. In addition, a new program announcement will solicit further studies of the basic CF defect and the Institute's intramural research on CF will be intensified. These initiatives reflect the Institute's strong and continuing commitment to unlocking the mysteries of CF through intensive investigator-initiated research.

Digestive Diseases and Nutrition

As a result of digestive diseases research, liver cancer has been linked with chronic active hepatitis. Researchers have found that some patients with long-term chronic active hepatitis have incorporated in the genetic apparatus of their liver cells the DNA of the virus that causes hepatitis B. The same viral DNA was found in some patients with liver cancer, who previously were hepatitis B carriers. The recent development of an effective vaccine against hepatitis B may thus contribute to marked reductions in liver cancer. Another discovery in digestive diseases is the finding that both the gut and the brain contain common peptide hormones. This signals possible interrelationships among different body systems, such as the digestive and central nervous systems. With these findings come tremendous opportunities for understanding the interactions of cells and the influence of cell-to-cell communication on health and disease.

At the same time, new and highly sophisticated fiber-optic endoscopes are enabling physicians to stuidy, diagnose and treat a vriety of conditions such as gastrointestinal bleeding. Using highly flexible scopes and probes, researchers are now able to examine directly, in patients, the normal and abnormal structure and function of previously inaccessible parts of the digestive system.

Research in nutrition has identified new effects of a recently discovered metabolite of vitamin D and demonstrated benefit in the treatment of bone disease. Patients with osteoporosis, a bone disease especially prevalent in the older population of women, have

been shown to improve calcium balance and experience increased bone mass when receiving such therapy.

Kidney, Urologic and Hematologic Diseases

End stage renal disease (ESRD) is a primary focus of the Institute's kidney research efforts. To bring additional and more vigorous research to bear on ESRD, the Institute will support two major initiatives. First, we will support new research projects to explore the natural history and mechanism of the chronic kidney diseases that frequently lead to ESRD, in an effort to prevent kidney failure. We will try to learn how and why some kidney disease patients undergo a relentless downhill course to chronic kidney failure, while others remain relatively stable. The roles of diet, metabolism, genetics, immunology, and other factors will be studied. Special attention will be devoted to diseases caused by immunological mechanisms, since they account for up to 50 percent of ESRD cases. Our second initiative will attempt to identify criteria to guide interventions in ESRD by examining nutritional, metabolic, biochemical, and other quantifiable variables. This research may enable physicians to determine more precisely in each patient when dialysis should be initiated, and to tailor dialysis better to individual needs.

We are pleased to report the successful development of a comprehensive approach to the evaluation and treatment of kidney stones, a major achievement in research related to the urinary tract. Tailor-made medical therapies now can be used to prevent the recurrence of up to 80 percent of various types of kidney stones in patients who are habitual stone-formers. Another target of ongoing research is concerned with benign enlargement of the prostate, a condition that affects nearly 80 percent of men over age 60, and for which 10 percent require surgery.

Blood diseases research is being spurred by remarkable advances in molecular genetics. Here, a new, quicker, less complex and less costly test for prenatal diagnosis of sickle cell anemia has been developed which does not involve the relatively risky procedure of taking samples of fetal blood. New techniques now permit more precise study of specific genes that control formation of the protein component of hemoglobin--the principal constitutent of red-blood cells. Research in molecular genetics now holds hope for preventing or better treating diseases of abnormal hemoglobin, such as sickle-cell disease and thalassemia, by chemical modification of defective genes or blood proteins.

Research Training

To maintain research momentum, we need to replenish scientific talent. Research training and career development, particularly for physician-scientists, receive special emphasis within NIADDK. To seize and pursue the vast research opportunities that now exist, we must engage young minds in the challenge of science and provide stability of research careers to productive investigators. Research training remains the wellspring of future scientific advances and an essential source of improvements in public health.

In conclusion, Mr. Chairman and Members of the Committee, the budget request for the Institute for 1984 is $426,394,000. I shall be happy to answer any questions you may have.

Biography of Dr. Lester B. Salans

NAME: Lester B. Salans, M.D.

POSITION: Director, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases

EDUCATION: B.A., University of Michigan, 1957
M.D., University of Illinois, College of Medicine, 1961

EXPERIENCE:
Director, NIADDK, 1982-present
Acting Director, NIADDK, 1981-1982
Associate Director, Diabetes, Endocrinology and Metabolic Diseases, 1976-1982
Chief, Cellular Metabolism and Obesity Laboratory, NIADDK, 1977-1982
Professor Adjunct, Dartmouth Medical School, 1978-present
Associate Professor, Dartmouth Medical School, 1971-1978
Head, Section of Endocrinology and Metabolism, Dartmouth Hitchcock Medical Center, 1968-1976
Chief Medical Resident, The Hospital of The Rockefeller University, 1967-1968
Fellow, National Institutes of Health Special Fellowship, The Rockefeller University, 1966
Post-doctoral Fellow in Endocrinology and Metabolism, Stanford University Medical Center, 1964-1966
Internship and Residency Training, Internal Medicine, Stanford University Medical Center, 1961-1964

RESEARCH INTEREST AND EXPERIENCE: Diabetes and obesity, mechanism of insulin action, intermediary metabolism

ASSOCIATION MEMBERSHIPS:

American Association for the Advancement of Science
American Diabetes Association
American Federation for Clinical Research
American Society of Clinical Investigation
American Society for Clinical Nutrition
Endocrine Society
Fellow, American College of Nutrition
Fellow, Council on Atherosclerosis, American Health Association
New York Academy of Sciences
Sigma Xi

EDITORIAL BOARDS AND JOURNAL REVIEWS:

American Journal of Nutrition
American Journal of Physiology
Diabetes
Endocrinology
Journal of Clinical Endocrinology and Metabolism
Journal of Clinical Investigation
Journal of Lipid Research
Metabolism
Science

SPECIAL AWARDS, CITATIONS,
OR PUBLICATIONS:

Phi Eta Sigma, University of Michigan, 1954
Alpha Omega Alpha, University of Illinois, College of Medicine, 1959
Mosby Scholarship Award, University of Illinois, College of Medicine, 1961
M.D., cum laude, University of Illinois, College of Medicine, 1961
Distinguished Public Service Award, Juvenile Diabetes Foundation, 1979
National Institutes of Health Director's Award, 1980
Senior Executive Service Performance Bonus, 1981, 1982
Author of more than 50 publications on diabetes, metabolism and obesity

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Questions Submitted by the Subcommittee

RESEARCH GRANTS BUDGET

Question: We would like to get your perspective on how the revised NIH budget for FY 1984 affects your Institute. How many additional new and competing grants will you get above the January budget -- and what further research will you be able to do as a result?

Answer: We will be able to support 191 additional new and competing research grants. This will enable us to fund approximately 30 percent of the approved applications to a priority score of about 180 rather than 22 percent of approvals at a priority score level of 170 which could have been funded under the January budget. These increases will be used to enhance each out of ten major programs and numerous subprograms but the specific projects will be chosen primarily on the basis of scientific merit as judged by the peer review system. In the area of end-stage kidney disease we plan specific new initiatives. A clinical trial to seek to identify a minimum window of physiologic indices for initiation of dialysis will be supported as a cooperative agreement (part of the regular grants mechanism) rather than as a contract as originally planned. We are also committed to announcing a request for applications on the natural history and mechanism of renal failure.

Question: It is our understanding that the January and April budgets both assume cuts in the average award for new and competing grants below what the average cost would be. For new grants this appears to be a difference of some $17,800 ($142,400 full cost vs. $124,600 in revised budget). How will this affect your Institute -- and to what extent will it start changing the scope and quality of the projects that are reviewed by your study sections?

Answer: This institute will reduce the direct costs of its competing awards by eleven percent from the computer model's projected study section recommendations and indirect costs will be further reduced by ten percent. We are less concerned about

a change in the quality of the projects which are reflections of the potentials and capabilities of the principle investigators than we are of the scope of the projects. We might see a reduction in the pace at which new ideas can be developed if decreased technical support, supplies and materials restrict the number of tests or procedures which can be conducted within a particular time frame, although we are confident the quality will remain high.

Question: Under your budget revision, the average NIH noncompeting grant award is projected to decrease by about $12,400 below what the full average cost would be ($143,100 full cost vs. $130,700 in budget revision). How will this affect your Institute -- and to what extent will it change the scope and quality of the projects that are reviewed by your study sections?

Answer: We have the same concerns about the scope and pace of research conducted under non-competing grant awards as we do about those conducted under new or competing awards. Reductions in funding could affect the scope or the level of effort which can be applied, either of which could diminish the project or extend the time necessary to attain the planned objectives.

RESEARCH CENTERS

Question: The Administration proposes to make cuts from the January budget in grants to specialized and comprehensive research centers. How does this affect your program -- and what will it do to research at those centers?

Answer: Under the current budget proposal, the twenty five centers for which future support has been planned would have their direct costs reduced by ten percent and their indirect costs by an additional ten percent. Funds for eighteen centers which will be due to re-compete for support have been eliminated. These represent approximately two-thirds of the Multipurpose Arthritis Centers program, one-third of the diabetes centers and one-fifth of the Clinical Nutrition Research centers. These have been difficult decisions but necessary to support our highest priority research.

CLINICAL TRIALS

Question: To what extent will any clinical trials be affected by the proposed cuts in research and development contracts and cooperative clinical research?

Answer: A planned contract on therapeutic pheresis in treating rheumatoid arthritis and systemic lupus erythematosis will be postponed. The clinical trial to seek to identify physiologic indices for initiation of kidney dialysis will be conducted under the grant mechanism and will be subject to cost reductions.

TRAINING

Question: The new budget proposes to eliminate the 5% stipend increase for predoctoral and post-doctoral training, to make further reductions from the January budget in the number of trainees, and to decrease the number of research career awards

to promising scientists. What effect will these steps have on your Institute's training program -- and what effect will it have on young people contemplating careers in biomedical research?

Answer: The institute has given very high priority to training and has maintained this program at very nearly the 1983 level and does not believe the slight decrease in the number of trainees and career awards will have any adverse impact on these programs, if this trend does not continue too long. The elimination of the 5% stipend increase is consistent with other proposals of the Administration regarding cost-of-living increases.

BIOMEDICAL RESEARCH SUPPORT GRANTS

Question: To what extent will the proposals to reduce funding for General Clinical Research Centers and Biomedical Research Support Grants affect biomedical research in general and your Institute's work in particular?

Answer: Nearly one-third of the investigators supported by this institute are also supported under these two programs. If this supplemental support is reduced, we anticipate that our grantees will need and request additional support from our institute. NIADDK grantees will have to provide for the loss of funds in these two areas from their own research project grant budgets or seek assistance from their institution as other sources.

MANAGEMENT OF FEDERAL FUNDS

Question: At a time when many budgets are going down, Congress has been increasing funding of the National Institutes of Health, including your Institute. We are concerned that these scarce resources be carefully and effectively used and that there be no basis for criticism of your management of this money. What assurances can you give us that your Institute is making careful and effective use of the appropriations we provide you?

Answer: In addition to the national advisory council which has primary responsibility for recommending final approval of our grant and training awards and the Board of Scientific Counselors which periodically reviews, evaluates and makes recommendations on our intramural research programs, this Instiitute makes extensive use of experts in the various fields and subspecialities to provide advice on both the overall program plans and the selection of projects to be supported in carrying out those programs. Each of the four divisions of the institute utilizes the appropriate members of the national advisory council as a subcouncil to review in depth and provide expert advise on the programs and plans of the division. Each division also uses ad hoc expert consultants to assist in specific areas such as review of the concept for and the development of the protocals for clinical trial and for periodic review during the trial itself. Special reviews are made of major program segments such as Multipurpose Arthritis Centers and Diabetes Research and Training Centers. Finally, this Institute receives continuing review and valuable advise from three national advisory boards: the National Arthritis Advisory Board, the National Diabetes Advisory Board, and the National Digestive Diseases Advisory Board.

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Question: Aside from the peer review system, what institutional arrangements do you have that serve to deter waste, fraud or abuse in the handling of federal funds?

Answer: While this institute has no programs separate or distinct from the Departmental or NIH-wide efforts in this area, our contracts officers, grants management officers and project officers are integral parts of the system for detecting or receiving and forwarding information on possible waste, fraud or abuse to appropriate authorities.

INSULIN PUMP

Question: The Committee has been most interested in the development of the insulin pump as a means of stabilizing blood sugar levels in the victims of diabetes. What success have you had with these pumps--and what problems are still to be solved?

Answer: Two general types of automated insulin delivery systems have been developed during the past several years. The "closed loop" system continuously monitors the patient's blood glucose levels and automatically regulates the rate of insulin administration in order to maintain near-normal levels of blood glucose. At the present time, the "closed loop" system is a large, expensive device that requires continual professional supervision and is therefore only suitable for use over relatively short periods of time on an inpatient basis. Further refinement of this system now awaits the development of a miniaturized, biocompatible sensor that will continuously monitor blood glucose levels on a long-term basis.

The "open loop" insulin delivery system consists of a miniaturized, programmable insulin pump and indwelling catheter that can be used by ambulatory patients in conjunction with a self blood glucose monitoring device. The "open loop" system is regulated by the patient in an attempt to deliver insulin at rates designed to accommodate meals, exercise, stress, etc. The success of this system is, therefore, totally dependent on intensive commitments by both the patient (to self blood glucose measurement) and by the medical support team.

Preliminary studies using extracorporeal "open loop" insulin pumps in conjunction with self blood glucose monitoring devices suggest that improved blood glucose control and other metabolic benefits are possible when these technologies are appropriately applied by highly motivated patients under the close supervision of experienced medical personnel. Although these preliminary results are very encouraging, neither the potential risks or benefits of this new approach to intensive management of insulin-dependent diabetes have been fully evaluated. In particular, the impact of intensive blood glucose control on prevention or amelioration of the long-term complications of diabetes yet remains to be determined. NIADDK's recently-initiated Diabetes Control and Complications Trial is a multicenter clinical study that has been designed to address this critical question.

In addition to this very fundamental question, there are also a variety of other problems that remain to be solved. These include the need for development of both stable insulin prepara-

tions that are suitable for pump use and non-irritating indwelling catheters that are appropriate for long-term insulin infusion. Furthermore, although preliminary studies now suggest that fully implantable "open loop" systems are technically feasible, additional research is needed to assess both the relative benefits of various insulin infusion sites, and the numerous physiological parameters that determine optimal rates and patterns of insulin delivery.

Question: To what extent do you view the pumps as a procedure to be used after conventional insulin therapy has been employed to achieve glucose control?

Answer: The "open loop" insulin pump, used in conjunction with a self blood glucose monitoring device, provides a new and potentially significant therapeutic alternative to conventional insulin treatment in diabetes. Preliminary studies now suggest that this new approach can provide improved control of blood glucose and other metabolites in highly motivated patients who are closely supervised by an experienced medical team. In addition, it has also been established that there are significant risks and costs assocated with the use of this new technology. Nevertheless, it has not been established that improved metabolic control will prevent, delay, or reverse the long-term complications of diabetes that are responsible for much of the morbidity and mortality associated with this disease. Until this fundamental question is resolved, it will not be possible to determine whether intensive insulin treatment actually offers a therapeutic advantage over conventional approaches to insulin administration. In this regard, the NIADDK has recently initiated the Diabetes Control and Complications Trial, a multicenter clinical study, to address this critical question. This trial, which is just now beginning a 2-year feasibility phase, has been designed specifically to compare intensive metabolic control and conventional management with respect to prevention and amelioration of the long-term complications of insulin-dependent diabetes.

SYNTHETIC HUMAN INSULIN

Question: When will synthetic human insulin be available to the public--and how will it differ in quality and side-effect potential from the animal product?

Answer: Within the past year, the Food and Drug Administration approved the marketing of synthetic human insulin produced by new gene splicing techniques. This new insulin is currently undergoing clinical testing, and it should become commercially available later this year. With respect to product quality and side effects, studies to date have not demonstrated any significant clinical advantages of synthetic human insulin over animal insulin except in rare cases where diabetics develop insulin resistance due to antibody formation or where there are allergic reactions to animal insulin.

MYCOPLASMA

Question: In its fiscal 1983 report, the Committee asked you to look into mycoplasma related causes of rheumatoid arthritis. We also asked that you examine relevant clinical data and take into account the possible importance of duration of treatment as a

factor. Where do you stand on this inquiry--and what are your findings? Don't you have data more recent than the 1971 clinical trial you refer to in your report?

Answer: We are currently preparing the report. It will be based on a thorough analysis of the world's literature on this subject which comprises 66 scientific articles published from 1939 to 1981.

In brief, the analysis revealed the following:

1) There have been many attempts to isolate mycoplasmas from the joints of patients with rheumatoid arthritis. Some have reported positive results; but other investigators were not able subsequently to reproduce there findings.

2) Similarly, of the many attempts to detect antimycoplasmal antibodies in the serum of rheumatoid arthritis patients (as a sign of past or current infection), such antibodies were detected by some investigators, but here again subsequent efforts to replicate and thus confirm these findings have not been successful.

3) Reviewing the therapeutic studies evaluating the efficacy of antibiotics directed against mycoplasma in rheumatoid arthritis patients, some uncontrolled clinical trials revealed benefit; others did not. A double-blind controlled clinical trial of low-dose tetracycline (an antibiotic) versus placebo over one year in 27 patients, published in 1971, revealed no significant benefit. To our knowledge, there have been no other clinical trials on this subject since that time.

Many medical specialists on arthritis, as well as the Arthritis Foundation, do not believe that tetracycline has a place in the treatment of rheumatoid arthritis. In June 1981, the Foundation issued a statement that no "researchers have actually proved that mycoplasma causes rheumatoid arthritis, nor is there any valid evidence that tetracycline can cure the disease or even be of benefit to its victims.

There appears to be a need for additional research in this area. NIADDK and NIH welcome applications for support of research, including proposals on the role of mycoplasma and potential antimycoplasmal treatments in rheumatoid arthritis.

JUVENILE ARTHRITIS

Question: What progress are you making against juvenile arthritis?

Answer: Clinical and laboratory studies have now clearly shown that juvenile arthritis is not one disease, as previously thought, but rather a group of at least six different distinct diseases. Some of these, such as rheumatoid arthritis and ankylosing spondylitis, are adult rheumatic diseases occurring in children. Thus, the totality of arthritis research on these diseases is important to juvenile arthritis. Other forms seem to begin only in children, these include the highly febrile form and

a special form in girls with few affected joints, eye involvement and antinuclear antibodies. Some of these have special tissue types as genetic markers.

NIADDK is supporting multi-center clinical trials testing the value in juvenile arthritis of antiarthritic drugs shown to be effective in adults with arthritis. In addition, there are special studies in the Arthritis Centers programs on juvenile arthritis, such as 1) model state demonstration programs in Missouri and Indiana, 2) outcome of juvenile arthritis in adults, and 3) immunologic research.

CYCLOSPORIN

Question: We understand Cyclosporin A has been successfully used in transplants in Canada. What do you know about this--and to what extent is this an important development in the field?

Answer: The current clinical trials in the U.S. now in their second or third year, indicate that Cyclosporin A has great promise as an immunosuppressive agent for kidney transplant patients. It is also having a dramatic impact on the success of liver transplants. Cyclosporin A is one of the most promising developments in the field of immunosuppressive therapy for transplantation. Cyclosporin A, a fungus metabolite, was discovered in Switzerland in 1972 and experimental tests of its efficacy in suppression of the immune response in animal recipients of transplanted organs were begun in 1975. Dr. Roy Y. Calne, Cambridge, England, showed Cyclosporin A's effectiveness in suppression of rejection of cadaver donor organs in its first clinical trial. Four U.S. institutions are conducting clinical trials of cyclosporin A: University of Minnesota, University of Texas at Houston, University of Pittsburgh, and the Brigham and Women's Hospital, Boston. These trials have shown that Cyclosporin A, when substituted for the current immunosuppressives, could: (1) reduce the number of rejection episodes markedly; and (2) decrease the infection rate (a frequent complication of immunosuppressive therapy) significantly. Dr. John Najarian (University of Minnesota) presented information about his controlled clinical trial recently and noted "this appears, thus far, to be a highly effective agent for suppressing the immune response in recipients of organ transplants without the adverse effect of increased infection." In this controlled trial, which has over 90 patients on Cyclosporin A and over 90 patients on traditional immunosuppressives, Dr. Najarian notes that because of the decreased number of rejection episodes, the dosage of the steroid, prednisone, which has deleterious side effects, can be reduced.

NUTRITION AND KIDNEY DIALYSIS

Question: You are participating in a study to look for alternative therapies to kidney dialysis, including nutritional therapy, as a means of holding down costs and improving the quality of life of patients. What is the status of the study--and what have you learned so far?

Answer: Nutritional therapy in ESRD is a complex subject compounded by our general lack of knowledge about the underlying

causes of ESRD, the absence of generally agreed-upon criteria for initiating dialysis, the tremendous variability that can exist among dietary regimens, and the need to plan carefully and systematically for all research studies involving humans. The National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) has conducted an extensive review of the literature and consulted with many eminent scientists in the field. Based on these efforts, the Institute has found that nutritional therapy in ESRD and that additional research in this area is needed. Such studies will take several years to complete. Careful research is the best means of providing the necessary information to make an informed judgment about nutritional therapy for ESRD. Specific steps taken to date by the National Institutes of Health include the following:

- Research on nutrition and kidney diseases supported by the National Institutes of Health has increased substantially during the past five years.

- NIADDK sponsored a conference on "Nutritional Therapy in Chronic Renal Disease," in April 1982. Participants included leading scientists in the field, from both academia and the private sector. Following the conference, NIADDK developed plans for two initiatives, which will include the study of nutritional variables in ESRD. The first initiative will investigate the natural history and mechanisms of the diseases leading to ESRD, thereby focusing on early kidney disease and possible nutritional/metabolic relationships. The second initiative will attempt to identify objective criteria for initiating interventions in ESRD, and attempt to determine whether nutritional therapy can delay the frequency of dialysis and/or postpone its onset.

NIADDK plans to announce both initiatives in Fiscal Year 1983 and to begin them in Fiscal Year 1984. Currently, NIADDK estimates that the first initiative will take three to eight years to complete, depending on the type and scope of proposals received in response to the Institute's solicitation. The second initiative will entail approximately five to eight years.

As a result of extensive liaison initiated by NIADDK program staff with investigators in the field, the Institute has recently received three grant proposals in Fiscal Year 1983 highly relevant to the relationship of nutritional/metabolic parameters in chronic kidney failure.

AVERAGE GRANT SIZE

Question: Last year we became aware that your applications for research grants were coming in much higher than anticipated when the fiscal 1983 budget was being formualated. The average increase was in the range of $20,000 to $30,000. We did provide you some additional funds to help make up the difference and to avoid your having to reduce grant size or reduce the number of grants. What has been the result of this effort -- and have you been able to catch up with the problem?

Answer: The additional funds were helpful in enabling us to support more research in all of our disease areas. However,

in spite of the additional funds and a somewhat lower average cost than originally projected, we have found it necessary to reduce all of our research grants by 5 to 6 percent and our center grants by 6 to 9 percent from projected study section levels in order to make research grant awards to a priority score of 180 in fiscal year 1983 and fund this Institute's portion of the stabilization level of 5,000 new and competing research project grants.

KIDNEY STONES

Question: What progress are you making in the effort to find means of dissolving kidney stones--and are there any successes to report?

Answer: There has been dramatic progress in treatment of kidney stones. Under NIADDK, Division of Kidney, Urologic and Hematologic Diseases support, five centers devoted to kidney stone research have delineated pathophysiologic mechanisms responsible for some kidney stone formation, devised medical therapy which is effective in preventing recurrence of stone formation in patients with this problem, and developed a shorter metabolic work-up for patients who are recurrent stone formers, that can be done on an out-patient basis.

Two new devices have been developed which permit renal stones to be broken up without surgery. The method developed in Munich, Germany, uses high energy (acoustic) shock waves, narrowly focused. At least five centers in the United States will acquire the necessary equipment to initiate trials of this technique within the next year. Almost 800 patients with kidney stones have been treated with this German method with over 98% success rate. The other method, utilizing ultrasound, needles, and nephrostomy tubes enables stones to be removed from the kidney without requiring a surgical incision. Using ultrasound equipment developed in Austria, urologists at the University of Minnesota, the Mayo Clinic, and the University of California, San Francisco, have had excellent success in breaking and removing stones from the kidney. In the near future, it is anticipated that these two non-surgical techniques for dissolution of kidney stones will be utilized increasingly in the United States.

GALLSTONES

Question: What drugs have been developed to dissolve gallstones--and are any of them effective and free of side effects?

Answer: Chenodeoxycholic acid, a bile salt, was studied in a randomized clinical trial involving 916 patients. When given in a dose of 750 mg per day, it caused complete dissolution of gallstones in 13.5% of patients and partial dissolution in an additional 27.3%.

Clincally significant liver toxicity occurred in 3% of patients, but it was reversible, clearing when the drug was withdrawn.

Clinically significant diarrhea occurred in 41% of the patients receiving this dose.

With doses of both 750 mg and 375 mg, the mean serum cholesterol increased by 20 mg/dl (8.7%) above enrollment compared to 10.7 mg/dl (4.6%) with placebo. Low-density lipoprotien accounted for most of the increase in total cholesterol. This increase in cholesterol could be associated with an increased risk of developing ischemic heart disease, especially in those with high initial values of other risk factors.

In other studies, larger does of chenodeoxycholic acid have been given and a larger percentage of gallstones dissolved has been reported. The extent and significance of liver toxicity and possible elevations of serum cholesterol in association with larger doses await further evaluation.

Ursodeoxycholic acid has also been shown to dissolve gallstones and early studyies suggest that it does not have comparable toxicity to chenodeoxycholic acid. However, we must await careful studies of the type performed on chenodeoxycholic before we can adequately evaluate the effectiveness and toxicity of ursodeoxycholic acid.

HORMONES AND APETITIE CONTRCL

Question: We understand that government scientists have discovered certain brain chemicals that apparently help control appetite and may decide whether people become fat or thin. What can you tell us about this -- and to what extent does it imply that new drugs could be developed to suppress appetite by tying up the receptor sites in the brain?

Answer: Scientists have shown that when the peptide hormone, cholecystokinin, is given to small animals, they take less food. Recent studies have been done on man and confirm that this hormone leads to satiety and smaller food intake. However, these experiments have only been performed in man for a single meal or a period of two to three days; therefore, it is not certain that the effect persists over a period of time, and thus diminishs obesity; further it is not known whether if the hormone is continued, it prevents obesity from recurring.

Another peptide hormone, bombesin, has been found to have an effect similar to cholecystokinin. This peptide may act either directly or by stimulating cholecystokinin. Bombesin, like cholecystokinin, is secreted in response to a meal. Bombesin has only been studied in small animals where, indeed, it has led to some weight loss. Studies in man are being contemplated. Until the long term effects and the possible risks and side effects of long term usage of these hormones, when given for obesity, has been determined, we can not be sure whether these early observations can be the basis of a useful therapy for obesity.

GASTRIC BALLOONS

Question: What is the current status of the use of so-called gastric balloons implanted in the stomachs of the obese to help them control their appetites? Do they have side-effects -- and could they be an alternative to surgical techniques?

Answer: Gastric balloons have been introduced into the stomach of man and then distended with about 500 cc of air to induce a feeling of satiety when the patient eats even a small amount of food. It was reported in Lancet that this procedure was done in five men for a period of 3 weeks, and there was weight loss.

At the meetings of the Federation for Experimental Biology and Medicine in Chicago during the past week, there was a report of the use of balloons in obese mice, and the report was that they indeed lost weight. This has not yet been tried in the United States in human beings. However, there are plans to investigate its use.

Their could be complications and side effects, for example, ulceration in the stomach. Further, the stomach may adapt over several weeks and the treatment no longer be effective. Until the risks have been evaluated as well as the long term effectiveness of the treatment, this procedure remains highly experimental. Moreover, as a long-term treatment for obesity, which is clearly a chronic disease, it seems unlikely that this approach will have much positive impact and therefore be an important part of the treatment of this lifelong disorder.

Questions Submitted by Senator Mark O. Hatfield

EPIDERMOLYSIS BULLOSA

Question: What identifiable steps have been taken to promote research in EB, or in a broader sense, to promote research in dermal-epidermal junctions? Dollars, bulletins, directives, requests for applications?

Answer: The NIADDK published an announcement of research interests in epidermolysis bullosa in the April 23, 1982, issue of the NIH Guide for Grants and Contracts. This announcement indicated our Institute's interest in supporting basic research into epidermolysis bullosa. To date only a single grant application that has been funded can be identified as having come in as a direct response to this announcement. Because of the experimental model used by that applicant, the grant was actually funded by the Dental Institute. In addition, the NIADDK supported a workshop on Disease Mechanisms in Epidermolysis Bullosa via an R13 grant mechanism, which was held in the spring of 1981. The report of that workshop is now being readied for publication. Finally, the NIADDK is co-sponsoring, along with the NICHD, a workshop on Morphogenesis and Malformations in Skin. This workshop will include a major section on dermal-epidermal junction research, as well as specific reference to epidermolysis bullosa. This workshop is to be held in September of 1983. At present the NIADDK is supporting 7 research projects dealing directly with epidermolysis bullosa, and many other projects in our Skin Diseases Program that may have an indirect bearing on this disorder.

EPIDERMOLYSIS BULLOSA

Question: Have any specific grant applications or funded applications dealt with questions specifically relevant to EB, and

if so, what percent of the total skin disease budget does this involve?

Answer: Grant applications dealing with questions specifically relevant to EB include grants dealing with dermal-epidermal interactions, collagen formation and destruction, as by collagenase and other enzymes, and mechanisms of blistering skin diseases, including EB but also including other blistering skin diseases. We support several projects via various mechanisms investigating these problems. These mechanisms include one Research Career Development Award, one program project, 11 regular research grants, and 2 New Investigator Awards. These 15 supported projects have a total budget of approximately $1.7 million. However, most of these projects are not totally committed to investigating questions of relevance to epidermolysis bullosa. Some of these projects are largely investigating questions of relevance, whereas others are only peripherally investigating questions of relevance to EB. Thus, of this total of $1.7 million, only approximately $700,000 can be identified as being devoted to questions specifically relevant to epidermolysis bullosa. This represents approximately 6% of the skin disease budget.

Question: What can be done to generate more research interest in EB and in studying the dermal-epidermal junction?

Answer: The publication of the program announcement in epidermolysis bullosa would be expected to generate interest in EB. It has been approximately one year since that announcement was published, and given the time delay between publication, the writing of the grant application, its receipt, review, and funding, it is not surprising that only one application has been funded as a result of this announcement. The workshop on Disease Mechanisms in Epidermolysis Bullosa certainly generated some additional interest in this area among those participants in the workshop. We would expect that the eventual publication of the proceedings of that workshop will also generate interest among individuals who were not able to attend the workshop itself. Similarly, the planned workshop on Morphogenesis and Malformations in Skin, in which there will be a section devoted to dermal-epidermal interactions with reference to EB as well as other diseases, would be expected to generate additional research interest. Beyond these steps, and the active discussion of the Institute's interest in supporting research in EB and in the dermal-epidermal junction that takes place at all research meetings when the question is put to the NIADDK staff, two other mechanisms of generating additional research interest come to mind. The first would be the further exploration of inter-Institute interests in research in this area. This is already under way as indicated by the joint sponsoring of the upcoming workshop on Morphogenesis and Malformations in Skin. In addition, research in EB and the dermal-epidermal junction will be part of the discussions of areas of common interest at the ad hoc Interagency Dermatology Working Group meeting later this spring. The second method of generating more research interest in EB would be the use of a specific request for applications. This mechanism necessitates the setting aside of specific money to support applications generated by the RFA. This step has not been taken because of the limited budget available to support skin disease research as a whole and the negative impact on skin disease research should part of this limited budget be set aside to support one area of research.

NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

STATEMENT OF DR. MURRAY GOLDSTEIN, DIRECTOR

ACCOMPANIED BY:

DR. JAMES B. WYNGAARDEN, DIRECTOR, NIH
WILLIAM MATTHEWS, BUDGET OFFICER, NINCDS
NORMAN D. MANSFIELD, DIRECTOR, DIVISION OF FINANCIAL MANAGEMENT, NIH
ANTHONY ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET, DHHS

BUDGET REQUEST

Senator WEICKER. Our next witness is Dr. Murray Goldstein, Director of the National Institute of Neurological and Communicative Disorders and Stroke.

The Neurological Institute conducts vital research bearing on diseases of the brain and central nervous system, among other areas.

The revised budget request for the Institute is $301.5 million, about the same as the amount requested in January, and $5.8 million above the fiscal 1983 level.

Dr. Goldstein, we welcome you and your staff. Please proceed.

Dr. GOLDSTEIN. Thank you, Mr. Chairman.

May I introduce Mr. William Matthews, the Institute's Budget Officer.

Mr. Chairman, the National Institute of Neurological and Communicative Disorders and Stroke is the focal point at the NIH for research on a very broad range of issues. These include the functioning and disorders of the brain and the spinal cord, hearing, and those uniquely human characteristics of language and speech.

OVERVIEW

Understanding the normal functioning of the brain is the key to prevention and improved therapy. The fundamental research areas being given emphasis are the bases of all human performance—memory, learning, and the brain's control of the functions of the body. Thus, the basic research on the brain supported and conducted by this Institute is providing the necessary background for understanding who we are, what we are, and how we perform.

In addition to understanding how the brain works, disorders of the brain and nervous system are being given targeted research attention. Examples of major problems that are being given high priority include developmental and genetic disorders of children.

This group of disorders takes an extraordinarily large toll in death and life-long disability since the nervous system is probably the most vulnerable organ in the body during the developmental period.

Stroke, the third leading cause of death, remains a major killer and crippler.

Head and spinal cord injury is the leading cause of death and disability following trauma and accidents, the fourth leading cause of death.

Dementia is a major affliction of our aging population and finally it has been demonstrated to involve a specific area of the brain.

Hearing loss afflicts 13 million of our citizens; and finally 600 other common and rare disorders.

Mr. Chairman, I am pleased to report that we are making steady progress against these devastating disorders. Broad scientific opportunities for research are now available; research teams are now in place; and they are applying their skills to developing the means to prevent and to treat these disorders that affect our most important organ, the human brain.

I trust my written statement is a useful summary of our national research effort in these areas.

I hope to be able to respond adequately to questions you and the subcommittee may have for me.

Thank you, sir.

RESEARCH OPPORTUNITIES AND NEEDS

Senator WEICKER. In the fiscal 1983 committee report, we directed that you conduct an evaluation of the research opportunities and needs of the Neurological Institute.

We indicated we would like a report made to the committee in about 6 months. Your preliminary report indicates we won't hear from you for about another year. Would you like to explain that?

Dr. GOLDSTEIN. Sir, I can now revise that timetable.

The process involves three steps. The first step was receiving permission through departmental channels to let a contract for consulting services. We have been informed by telephone by the Department that we now do have that permission and could move ahead with the second and third steps.

The second step involved the Institute of Medicine. We have contracted with and have just received a report from the Institute of Medicine which provides us with the outline of substance that needed to be included in the study. We have a report of the Institute of Medicine now available to us.

The third and final step is the release of an RFP, a request for proposals, asking scientific groups and contractors to bid on doing the study outlined by the Institute of Medicine. The RFP will be available to the public at the end of this week.

We are proposing a 4-month study period. Therefore, sometime in the late summer or early autumn, we will be able to provide this committee with that study.

COMPETING GRANTS

Senator WEICKER. Now, to get to the matters that relate to the competing grants, what is the revision in numbers of competing grants for your Institute?

Dr. GOLDSTEIN. Sir, our original estimate was 394 competing grants. The level is now 524, an increase of 130 competing grants.

Senator WEICKER. And to the question on your matter of choice in this as to numbers or dollars, how would you respond to that?

Dr. GOLDSTEIN. Sir, as an Institute Director, I do hope that I am responsible enough to be permitted flexibility. I must have the chance to seize the opportunity as it presents itself.

Within the broad guidelines that have been given to us, I believe this budget does give me flexibility. As Dr. Wyngaarden explained, we would not propose to cut every competing grant. We would only cut those in which, in our own judgment, work could be delayed or spread over a broader period of time.

In other grants, we won't cut a single dollar.

We have within the NINCDS three major priorities.

The first, we have already discussed, investigator-initiated research. That is the system that might be named the key to our research effort.

Second, research training.

And finally, our intramural research program. All three of these activities will continue to receive first priority as they did this year. The other activities are important, but they support those three primary activities.

CLINICAL RESEARCH CENTERS

Senator WEICKER. Now in your Institute, on the priority base, is it correct that two of the following would not be funded:

The Research Center in Cerebrovascular Disease, Cornell University Medical Center; Pathogenesis and Treatment of Multiple Sclerosis, Yeshiva University; and the Center for Clinical Research in Epilepsy, University of Washington?

Dr. GOLDSTEIN. That is correct.

Senator WEICKER. Two of those three will be dropped?

Dr. GOLDSTEIN. That is correct.

Senator WEICKER. Has that decision been made yet?

Dr. GOLDSTEIN. No, sir, we have not yet received the scientific evaluation of the three. It would be a scientific basis decision rather than a policy issue.

Senator WEICKER. I have been discussing with other Directors the matter of research centers as it applies to competing grants. What about the other areas, continuation of competing grants, the applied research, or what happens there?

Dr. GOLDSTEIN. Sir, in terms of our research center program, this happens to be an instant in time in which only three centers are up for competing continuation support. So essentially, the major thrust of the center program will continue. This happens to be an accident of timing.

CLINICAL TRIALS

The second area of postponement is that of clinical trials. We will be required to postpone several clinical trials probably until 1985.

Senator WEICKER. Counsel has a good question while you are there. What clinical trials do you plan to postpone?

Dr. GOLDSTEIN. One, a clinical trial on a cochlea ear implant. This is a device which when implanted into the inner ear is showing very good evidence that people who are deaf can in fact now perceive sound. I mean persons who are totally deaf; they can hear nothing.

This device will permit them to perceive sound—a door closing, a telephone ringing, an automobile horn honking.

A problem that we want to look into is the issue to which kind of specific deafness will these devices be applicable?

The second is again in the area of hearing. There is a disorder known as otosclerosis in which the bones in the middle ear become fixed. We now have a chemical that we believe may loosen those bones and restore their function. If true, this form of hearing loss might be able to be eliminated.

At the moment, the only therapy is surgical intervention and it has the hazard of surgery.

Third is a drug when used in treatment during the acute phases of multiple sclerosis would appear to protect the brain and spinal cord. We hope this drug will become available in the very near future. Under our present budget plan, we would postpone the trial of this new drug.

A fourth is a treatment for peripheral neuropathy in diabetes. In addition, we were planning clinical trials in the area of stroke and in spinal cord injury.

Senator WEICKER. Let me say this to all the heads of the Institutes: We obviously don't have enough time to go through this particular question with each one of you. I would appreciate a response to the record by each one of the Directors as to what clinical trials are being postponed on the basis of the reallocation of moneys within the budget along the lines of what Dr. Goldstein responded.

ROLLER COASTER FUNDING

Is there not a drawback in terms of the research community to what I call the roller coaster type of funding in the research area? Doesn't it tend to discourage those persons that look to research as a career?

Dr. GOLDSTEIN. Yes.

HUNTINGTON'S DISEASE

Senator WEICKER. Several years ago, you initiated a study in Venezuela to study several large families with an unusually high incidence of Huntington's disease.

What results are you getting from this study, and have you identified anyone who inherited the Huntington's gene?

Dr. GOLDSTEIN. Yes, sir. This study is one of the most successful ef-

forts we have had. Field team No. 3 right at the moment is at Lake Maracaibo. In villages surrounding the lake, there is a collection of native Venezuelans who a number of years ago happened to have a visitor from a foreign ship; a sailor, who unfortunately was rather promiscuous and visited with several of the native women.

It turned out that this sailor had Huntington's disease.

The key to this study is that we now have a colony of people with a very high incidence of Huntington's disease, all due to a single gene defect from that particular man. Because these are isolated villages with few other people living near it, there is a great deal of intermarriage.

There are two important opportunities in the community.

First of all, we have never had a population in which we could find out what might occur if both the mother and father had Huntington's disease and had a child before either one of them recognized it. This is what we call the double dose, the fact that the child might inherit the gene from both the mother and father.

The issue is: Would that child die before birth in utero or if it did develop, would we have such an overwhelming biochemical change that we would be able to measure it and, therefore, identify specifically what biochemical change has occurred?

We have been able to identify—and that is one of the reasons the team is back in the field now—we believe eight children whose mother and father both have the disease. If that is true, we may have a double-dose marker; we have the probability of being able to identify the specific gene, specific enzyme, which causes this disease.

That marker will be tremendously important because once we identify that gene and that protein it controls, we would then be able hopefully through replacement therapy to substitute the protein that is needed and perhaps prevent the expression of the disease.

That is where we are right at the moment, sir, in that particular study.

PREPARED STATEMENT AND SUBMITTED QUESTIONS

Senator WEICKER. Dr. Goldstein, thank you very much.

There are other questions for response to the record. I appreciate it, and thank you.

[The information follows:]

Statement of Dr. Murray Goldstein

I am pleased to report to you today at a critically important time in our nation's research program aimed at the prevention and treatment of the devastating disorders of the brain, the nervous system, hearing, and those uniquely human characteristics, speech and language. The National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) is the focal point at the National Institutes of Health (NIH) for research in these areas. Its responsibilities encompass significant problems of health and disease including stroke--the third leading cause of death, and head and spinal cord injury--the major cause of death and disability due to trauma.

The complexity and vulnerability of the nervous system explain its over 600 disorders, which in the aggregate, parallel the public health consequences of the great killers of our time--heart disease, cancer, stroke and trauma. Of equal importance is the brain. It remains the great unknown in human biology--as yet a mysterious organ that is the center of who we are, what we are and what we will be. I am pleased to report that the scientific mechanism is in place to explore, with vigor and reasonable probability of success, the central nervous system processes of brain function--perception, integration, memory storage and retrieval, and the control of performance and behavior.

I want to bring this distinguished subcommittee up to date regarding the continuing veritable explosion of knowledge in the neurosciences and communicative sciences. This past year has seen a continuation and even an acceleration of this trend. One sign of this great productivity is the awarding of the prestigious Albert Lasker Clinical Medical Research Award to an NINCDS intramural research scientist, Dr. Roscoe O. Brady, chief of the NINCDS Developmental and Metabolic Neurology Branch. He discovered the specific enzyme deficiencies responsible for a class of developmental disorders; Gaucher's, Niemann-Pick, and Fabry's diseases. Dr. Brady's research on replacement of the missing enzymes has great promise for cure and, hopefully, for the sought-after prevention for these diseases and other lipid storage diseases, such as Tay-Sachs.

The diseases under NINCDS purview are particularly devastating. The Institute is charged with research for the diseases that usually strike the elderly, for example, stroke, Alzheimer's disease, hearing impairments, and Parkinson's disease. The Institute is also responsible for research on disorders that attack the young, for example, spina bifida and neural tube defects, tuberous sclerosis, neurofibromatosis, Tay-Sachs, Gaucher's disease, cerebral palsy, muscular dystrophy, and autism. Others, such as spinal cord injuries, myasthenia gravis, and multiple sclerosis which attack young adults, are also the responsibility of the Institute.

Recent research has been extremely productive and promising. We are beginning to understand the ways in which nerve cells communicate with each other and with other cells. Our Institute's intramural scientists have been among the leaders in identifying new neurotransmitters and neuromodulators. These chemical substances provide communication between nerve cells. Identifying and understanding individual neurotransmitters is crucial to an understanding of the functioning of the brain and central nervous system in normal and abnormal or diseased states.

Advances in stroke prevention and treatment continue to be made. For example, improvements in neurodiagnostic technology for non-invasive evaluation of carotid artery and subclavian artery disease have been perfected. Scientists are using similar techniques to detect atherosclerosis of intracranial blood vessels and to test various therapeutic regimens. Changes in the major intracranial arteries before and after therapy can now be followed at a patient's bedside.

Clinical research related to epilepsy has been very productive. Four new anticonvulsant agents have been developed and licensed, most recently clorazepate in 1981. A multicenter clinical trial is currently testing promising drugs for a relatively common form of epilepsy for which existing drugs are not effective. We are now initiating a multi-institutional controlled clinical trial for the prevention of epilepsy after head injury, a too common consequence of automobile and athletic injury.

Sensitive tests to detect antibodies directed against certain molecules in muscle membranes have also been developed. These tests make possible earlier, more accurate, diagnoses of such diseases as myasthenia gravis or muscular dystrophy which may be caused by abnormal molecules in the cell membrane.

We are also beginning to improve our understanding of dyslexia and other congenital learning disorders. Abnormal cell migration patterns have been revealed in the left temporal lobe of a few patients with these diseases. Recent studies have shown that many speech and language disorders, e.g., stuttering, and language learning disabilities occur repeatedly over several generations in some families.

It is, of course, impossible to discuss all of the NINCDS accomplishments and needs in a brief statement. I've chosen to highlight four areas this year: metabolic imaging, trauma, orphan drugs, and hearing.

Metabolic Imaging

The past decade has produced a vastly improved imaging technology that allows us to see the human body in entirely new ways. These techniques are helping us understand the way the brain and the central nervous system work in health and disease. The computed tomography (CT) scan has now found its appropriate place in clinical practice as well as in research and provides finer anatomic imaging than ever before. Even more exciting are the newer methods, positron emission tomography (PET) scanning and nuclear magnetic resonance (NMR) spectroscopy. These methods reveal the actual functionings of the brain. They provide metabolic images and, literally, show us the human brain as we have never before been able to see it. PET and NMR are noninvasive and, while each uses a different medium, neither requires large amounts of potentially harmful radiation. Diseases under investigation with PET include Alzheimer's disease, brain tumors, epilepsy, Huntington's disease and amyotrophic lateral sclerosis (ALS).

Trauma

Trauma is the leading cause of death in the United States for individuals from one year old to forty-four years of age. Accidents

killed 105,000 Americans in 1980 and, according to the National Safety Council, cost the American public $83.2 billion. The recent report, Health, United States, shows an increased death rate for only one age group, those 15 to 24, in large part, because of auto accidents and sports injury. We believe that more than 60 percent of deaths due to trauma result from injuries to the brain or spinal cord. Young males between the ages of 15 and 24 are most likely to suffer head injury and have the highest probability of serious spinal cord injury. The problem is a serious one, perhaps most tragic because it is the young who suffer.

The NINCDS is the focal point at the NIH for research related to trauma of the nervous system, brain, and spinal cord. We know that injuries which do not cut the spinal cord initiate a reaction that ultimately causes paralysis and we are working to define the specific events and, ultimately, to prevent the paralysis. We have learned that changes in blood flow and metabolism are associated with spinal cord trauma and that a multifaceted therapeutic approach is needed to prevent or ameliorate the secondary effects of injuries, including paralysis. Other studies have shown that the sympathetic nervous system may also exacerbate spinal cord trauma as may the natural pain-killing substances, or opioids. Scientists are now investigating naloxone and thyrotropin-releasing hormone (TRH), substances that "block" the effects of the opioids and may assist spinal cord recovery. An added problem here is that patients with severe injuries also need the very "pain killer" medications that may increase the risk of paralysis.

Yet, because paralysis often results, prospects for neural regeneration must be improved. Currently, once the spinal cord is severed, paralysis is permanent. Investigations of the brain and spinal cord are disclosing the ability of the intact portion of the injured nervous system to activate existing but unused nerve cell networks. Work is actively proceeding to identify those factors which will promote such nerve growth and restore function.

Scientists funded by NINCDS are also working on neural prostheses. These are electronic devices that replace lost function in neurologically impaired individuals. Neural prostheses may someday permit patients to stand and perhaps to walk without using crutches and other similar supports. Clinical trials of prostheses to aid in bladder evacuation in humans are now in progress; preliminary results are very encouraging. Work on using neural prosthetic techniques to restore the functional use of the hand in quadriplegic patients is also proceeding. We are very excited about recent work with electrical stimulation techniques that allow paralyzed muscle to function by creating controlled contractions of the muscle.

The NINCDS has served as the NIH lead institute in relation to other agencies and departments on trauma to the central nervous system. The problem is extremely complex and more research is needed, but there is new hope that paralyzed hands will again move, grasp, and function, and that paralyzed legs will someday walk.

Orphan Drugs

Development of orphan drugs is of special concern to the NINCDS because many neurological diseases affect relatively small numbers of people. Tourette's syndrome and myoclonus are examples of presently incurable rare disorders that require long-term therapy to ameliorate

or control symptoms but for which there has been little commercial incentive to the private sector.

The Orphan Drug Act provides the framework for an increasing partnership among government, private industry, and the biomedical research community to make greater strides in developing much needed medications.

The NINCDS Antiepileptic Drug Development Program interacts with industry in a systematic fashion, using Federal resources primarily for screening and acute toxicity testing. Industrial resources are used for synthesis and pharmacokinetic studies. Both industrial and Federal resources are used to fund clinical trials. This program will be our model for orphan product development in other areas.

The success of our Antiepileptic Drug Development Program is due, in part, to our understanding of epilepsy and the nature of the disease. No effective drug substances exist for many other rare neurological diseases. In most cases, we do not yet understand the diseases sufficiently to design useful drugs. The problem, then, involves far more than failure to test available substances or to market already evaluated drugs for rare diseases. Rather, in many instances we are confronted by a total absence of useful or potentially useful products. We hope that FY 1984 will see the invention and discovery of effective drugs for more neurological diseases.

Hearing

At least 1.5 million people are totally deaf or have hearing loss so profound that they cannot hear conversations, telephones, traffic noises, or fire alarms. Another 2 million have serious hearing handicaps, while approximately 10 million more suffer some significant hearing impairment.

Hearing is a complex process involving the ear and the brain. Impairments in the ear do not permit a signal to reach the brain; impairments in the brain do not permit the signal to have any meaning. Noninvasive methods can now detect electrical activity in the brain produced by sound transmission into the ear. NINCDS-supported studies have brought the goal of "prescription" fitting of hearing aids to near reality and have advanced the development of prostheses which may partially restore sound cues for the profoundly deaf adult. Biochemical studies of the auditory cortex are describing how the sound signal is modulated and acted upon so that it can be transmitted to brain centers for perception.

As a result of the explosion of new knowledge in the neurosciences, we are steadily increasing our understanding of how the brain and nervous system function. The ongoing translation of this knowledge into the prevention and treatment of neurological and communicative disorders remains our ultimate goal. The intensification of our efforts in the areas such as brain imaging, trauma, orphan drugs, and hearing holds the promise for significant progress in the future.

In conclusion, the budget request for the National Institute of Neurological and Communicative Disorders and Stroke for 1984 is $301,554,000. I am honored to have the privilege of sharing this information with you and will try to answer any questions you may have about these matters.

Biography of Dr. Murray Goldstein

NAME:	Murray Goldstein, D.O., M.P.H.
POSITION:	Director, National Institute of Neurological and Communicative Disorders and Stroke
BIRTHPLACE & DATE:	New York, New York; October 13, 1925
EDUCATION:	B.A., New York University, 1947 D.O., Des Moines Still College of Osteopathic Medicine, 1950 M.P.H., University of California, School of Public Health, 1959
EXPERIENCE:	Director, NINCDS, 1982-present Acting Director, NINCDS, 1981-1982 Deputy Director, NINCDS, 1978-1981 Medical Officer, Commissioned Corps, PHS (Assistant Surgeon General), 1953-present Director, Stroke and Trauma Program, NINCDS, 1976-1978 Director, Extramural Programs, NINCDS, 1961-1976 Visiting Scientist, Mayo Clinic and Graduate School, Rochester, Minnesota, 1967-1968 Chief, Special Projects Branch, NINCDS, 1960-1961 Assistant Chief, Research Grants Review Branch, DRG, 1959-1960 Acting Chief, Section on Virus Diseases of the CNS, Bureau of Acute Communicable Disease, California State Department of Public Health, 1958 Director, Epidemiology and Biometry Training Grant Program, DRG, 1956-1958 Assistant Chief, Grants and Training Branch, NHI, 1953-1958
ASSOCIATION MEMBERSHIPS:	American Academy of Neurology American Association for the Advancement of Science American Heart Association, Council on Stroke American Neurological Association American Osteopathic Association Association for Research in Nervous and Mental Disease Society for Neuroscience The American Parkinson Disease Association, Medical Advisory Board Eisenhower Institute for Stroke Research United Cerebral Palsy Research & Educational Foundation Board of Directors Consultant (Neurology), Pan American Health Association Consultant, World Health Organization Program on Neurosciences World Federation of Neurology International Brain Research Organization Commission on Alternative Health Care, U.S. Olympic Council on Sports Medicine

SPECIAL AWARDS, CITATIONS, OR PUBLICATIONS:

Beta Alpha Epsilon; Biology National Honor Society, NYU
Psi Chi; Psychology National Honor Society, NYU
Sigmi Alpha; Osteopathic Scholarship National Honor Society; College of Osteopathic Medicine
Delta Omega; Public Health National Honor Society; University of California
Doctor of Science (Hon); Kirskville College of Osteopathic Medicine
Doctor of Laws (Hon); New York Institute of Technology
Certificate of Merit; American Neurological Association
2nd Vice President; American Neurological Association
Silver Star; Purple Heart, U.S. Army
Meritorious Service Medal; Public Health Service
Associate Editor, Stroke, A Journal of Cerebral Circulation, American Heart Association
Editorial Board, Osteopathic Annals
Editorial Board, International Journal of Neurology
Editorial Board, The Journal of Neuroepidemiology
Author of over 20 scientific papers and monographs

Questions Submitted by the Subcommittee

NEW BUDGET FOR 1984

Question: We would like to get your perspective on how the revised NIH budget for FY 1984 affects your Institute. How many additional new and competing grants will you get above the January budget?

Answer: NINCDS plans to award 524 competing new and renewal research project grants in 1984, an increase of 130 grant awards over the January budget level of 394 grants and 55 grants over the 1983 level of 469 grants.

Question: What further research will you be able to do as a result?

Answer: The additional grant awards will support high priority investigator-initiated research opportunities in basic and clinical research in areas such as Alzheimer's disease, trauma of the nervous system, disorders of hearing, speech and language, central nervous system regeneration, neuromuscular disorders, and research on neurological disorders of early life such as genetic disorders and congenital abnormalities.

Question: It is our understanding that the January and April budgets both assume cuts in the average award for new and competing grants below what the full average cost would be. For new grants this appears to be a difference of some $17,800 ($142,400 full cost vs. $124,600 in revised budget). How will this affect your Institute--and to what extent will it start changing the scope and quality of the projects that are reviewed by your study sections?

Answer: For the April 1984 budget, our projection for NINCDS competing research projects is $135,639 for full average cost and a reduced cost of $111,712, a difference of $23,927. This 1984 average cost is about a 5% increase over the 1983 average cost of $106,817, offset by a 3% reduction attributable to th proposed reduction in indirect costs for 1984. When a grant is awarded at "full cost", the amount is based on the recommendations of the scientific merit review panel. These recommendations are based on peer reviewers' judgement of the dollars needed to do the research. When awards are made at amounts less than that recommended by the peer reviewers, the research may proceed at a slower rate, and/or specific portions of the proposed research plan would be deleted or deferred. Thus, the projected reductions would have their major effect on the scope of individual projects rather than their quality.

Question: Under your budget revision, the average NIH noncompeting grant award is projected to decrease by about $12,400 below what the full average cost would be ($143,100 full cost vs. $130,700 in budget revision). How will this affect your Institute--and to what extent will it change the scope and quality of the projects that are reviewed by your study sections?

Answer: We have projected, for NINCDS noncompeting research projects, that reductions would be somewhat less than the average for NIH as a whole. The full cost amount for noncompeting awards is $129,102, while the projected 1984 average cost would be $119,244. This represents a difference of $9,858. Noncompeting awards represent commitments for future years of grants previously reviewed and now active. These commitments are based on peer review assessments of funds needed in future years for optimal progress. If future years are not awarded at the amounts previously recommended, the grantee must make adjustments in either the rate of progress or the scope of the research, or both. The overall quality of the research should be affected only minimally.

Question: The Administration proposes to make cuts from the January budget in grants to Specialized and Comprehensive Research Centers. How does this affect your Program--and what will it do to research at those Centers?

Answer: Three research Centers funded by the NINCDS are due for competitive renewal in FY 1984. The requested budget will permit us to make a renewal award for one of the three, depending on the scientific merit assessment of the three requests for renewal. The three Centers involved are:

1. Research Center in Cerebrovascular Disease, Cornell University Medical Center, New York, New York. Dr. Fred Plum is the Principal Investigator.

2. Pathogenesis and Treatment of Multiple Sclerosis, Yeshiva University, New York, New York. Dr. Murray Bornstein is the Principal Investigator.

3. Center for Clinical Research in Epilepsy, University of Washington, Seattle, Washington. Dr. Arthur Ward is the Principal Investigator.

Question: To what extent will any clinical trials be affected by the proposed cuts in research and development contracts and cooperative clinical research?

Answer: The President's Budget which was revised in April, 1983 proposes a delay in initiation of clinical trials on: implanting electronic devices into the inner ears (cochlea) of profoundly deaf persons; use of promising modalities to modify the immune system's response to multiple sclerosis; the use of sodium fluoride to prevent development or progression of sensorineural deafness associated with otosclerosis; and moving into full phase study of the effects of tight blood glucose control on development of the neurological complications of diabetes. NINCDS would also postpone development and subsequent clinical testing for orphan products for rare diseases and for stroke and spinal cord injury.

Question: The new budget proposes to eliminate the 5% stipend increase for predoctoral and postdoctoral training, to make further reductions from the January budget in the number of trainees, and to decrease the number of Research Career Awards to promising scientists. What effect will these steps have on your Institute's Training program?

Answer: NINCDS maintains the same number of trainees as proposed in the draft budget in January. Elimination of the 5 percent stipend increase would have the greatest impact on those young persons who recently received their doctoral degree. Stipends for research training of clinical scientists would become less competitive with other clinical training salaries.

Reducing the number of Research Career Awards means that eleven fewer candidates could be given the opportunity for support to allow their development as independent scientists.

Question: What effect will it have on young people contemplating careers in biomedical research?

Answer: The effect of postponing the 5% stipend increase included in the January budget is not clear. While one could argue that the heightened competition for many positions should provide training only to the very best students, the competition is already so high that it can be anticipated that the number of awards to even the very best students would be reduced. Recognizing these possible effects of eliminating the stipend increase in 1984, the decision was made that it is preferable to postpone the proposed stipend increase than to drastically decrease the number of trainees supported.

Reduction in the number of Research Career Awards could hamper the development of those who would be qualified to receive them, and may further reduce the numbers of physician/scientists who serve as teachers and role models in research settings conducive to the development of young investigators.

Question: To what extent will the proposals to reduce funding for General Clinical Research Centers and Biomedical Research Support Grants affect biomedical research in general and your Institute's work in particular?

Answer: The proposals to reduce funding for the General Clinical Research Center (GCRC) and the Biomedical Research Support (BRS) grants were two reductions necessitated by the decision to fund 5,000 new and competing renewal research project grants within the same total dollar level as in the January budget.

The proposal to reduce the funding for GCRC awards by $2,021,000 would allow the Division of Research Resources to maintain funding for all 74 of the existing centers, although at a reduced level, by careful negotiation of each Center award. As a result, there would be some reduction in the core support that the centers provide to investigators working on NIH supported research project grants. In 1982 the GCRC provided the clinical research environment for principal investigators who hold a portfolio of 1,298 NIH-supported research grants valued in excess of $200 million.

The work of the National Institute of Neurological and Communcative Disorders and Stroke (NINCDS) would be affected by the proposed reduction in GCRC funding. In 1982 more than 58 NINCDS supported research grants costing $11,932,508 relied upon the trained staff, research beds, equipment and clinical environment provided by the GCRC to carry out research and research training efforts on neurological disorders such as stroke, epilepsy, spinal cord and head injury, multiple sclerosis, Parkinson's disease, Alzheimer's disease, Huntington's disease, Reye's Syndrome, amyotrophic lateral sclerosis, and communicative disorders of hearing and speech.

The Biomedical Research Support grant program awards funds to research institutions based on their level of PHS research grant support. These funds complement or supplement project grants by providing for pilot research, support of new investigators, centrally shared instrumentation, interim support and emergency funding. In FY 1982, BRSG funds were used to support nearly 9,000 of such research activities in 516 grantee institutions. The proposed reduction in the BRS grant activity of $24,657,000 would result in 52% reduction in the average size of all BRS awards. As such, 52% of research activities at the institutional level that are currently supported by BRSG awards would have to find other sources of funding.

The work of the NINCDS would be affected by the proposed reduction in ERS funding. In 1982 more than 277 NINCDS supported research grants costing $25,920,966 were awarded to Institutes which also relied upon the flexible funding provided by the BRSG award mechanism to supplement or complement their research efforts aimed at basic and clinical research and research training in the neurological and communicative disorders.

STUDY OF RESEARCH OPPORTUNITIES

Question: In our Fiscal 1983 Committee Report, we directed that you conduct an evaluation of the research opportunities and needs of the Neurological Institute. We indicated that we would like a report made to the Committee in about six months. Your preliminary report indicates we won't hear from you for about another year. How do you explain this?

Answer: The highlights of the actions we have taken include:

- o A request for permission to utilize the contract mechanism was completed and submitted for clearance through Department channels on January 26, 1983.

- o Verbal approval to proceed was granted by the Office of the Assistant Secretary for Management and Budget, DHHS, on March 18, 1983.

- o The Institute of Medicine convened a panel of experts in the neurological and communicative sciences on March 21, 1983, to develop a plan for the substantive issues to be included in the study.

- o The plan developed by the Institute of Medicine was incorporated into a request for proposals (R.F.P)

- o A request for proposals to conduct the study was released on April 13, 1983.

It is anticipated that a contract will be awarded on or before July 1, 1983. The study is to be completed within 120 days following the award of the contract. Completion of the study is therefore anticipated to occur on or about November 1, 1983.

Question: Your preliminary report states that you will do an in-depth assessment of research opportunities in the "neurological and communicative sciences". Is this terminology designed to embrace research on stroke, one of your main areas of work, or did you leave out "stroke" deliberately?

Answer: The terminology is designed to embrace all the neurological and communicative sciences and disorders. Since stroke is a neurological disorder, research opportunities and needs in the area of stroke will be addressed.

Question: We also directed that you ought to lay aside some $800,000 for the study. We assume you will make at least this amount available--and that your study will cover the cost of future research opportunities and needs.

Answer: The NINCDS intends to make available all necessary funds to conduct a study of research opportunities and needs in the neurological and communicative sciences. Since the proposals have not yet been received and evaluated, it is not possible to give a precise estimate of the final negotiated cost of conducting this project and producing the requested report. All funds necessary will be made available to support the study. The study will include an assessment of the needs required to address the identified research opportunities.

SPINAL CORD REGENERATION

Question: Our Committee has been continuously concerned with your work in the field of spinal cord regeneration. We recognize the complexity of the matter, but remain hopeful that you will make progress in this important area. What can you tell us about your plans for research in Fiscal 1984--what goals you hope to reach and how much you plan to spend?

Answer: Research on regeneration of the central nervous system remains one of the highest priorities of the Institute. Studies to date have reinforced the hypothesis that spinal cord neurons have the necessary intrinsic machinery for regenerating their severed or injured processes. There is still uncertainty about the factors which prevent regeneration in the central nervous system such as mechanical obstruction by connective tissue and glial scars, lack of chemical influences to nurture the growing neurites, and the absence of suitably oriented guiding pathways. The NINCDS supports investigators who are now at the cutting edge of neuronal molecular biology, which should provide answers to many current and future questions relevant to regeneration of the injured spinal cord. Work on simple nervous systems, as well as in mammals, is gradually yielding information that should lead to methods for controlling the regenerative process in humans. Among the factors under scrutiny and scheduled for future study are the chemical factors sustaining and accelerating nerve cell growth; trophic factors and guidance cues; hormonal and enzymatic influences; intracellular signals and metabolism; the extra-cellular milieu and matrices; axonal transport and neurite extension; specificity in re-establishment of neural connectivity; and the functional consequences of remodelled neural circuitry. NINCDS will continue to support the multiple avenues of research pertinent to neural regeneration and to initiate new studies that promise to bring the ultimate goal of restitution of spinal cord function to fruition. The 1984 estimate for NINCDS research on spinal cord injury and regeneration is $19,100,000.

Question: The "60 Minutes" television program last year displayed interest in experimental work in which computer-generated electrical impulses bypassed the injured spinal cord to activate long-dormant leg muscles. With much assistance, the victims walked a bit. What do you make of this sort of approach?

Answer: The experimental work depicted on "60 Minutes" in which computer-generated externally applied electrical impulses were utilized to activate leg muscles is a useful approach to the development of neural prostheses. While this preliminary report is encouraging as a basis for rehabilitation, additional research needs to be carried out before ambulation can be achieved. The Institute will continue to encourage and foster research on regeneration of the central nervous system, the effects of injury on the nervous system, and the development of prosthetic devices to aid those with spinal cord injuries.

ORPHAN DRUGS

Question: Congress last year passed the Orphan Drug Act which is designed to support the development of therapeutic drugs for which there is not much of a market. Since drug therapy can play a big role in your research, how do you view the value of this legislation to your work?

Answer: The NINCDS anticipates that the Orphan Drug Act will facilitate the work of the Institute. The liaison and public information activities of the Department's Orphan Products Board will encourage investigators to conduct research on orphan drugs and rare diseases. The financial incentives embodied in the Act should encourage private industry to assume further commercial development

of orphan products discovered through NINCDS supported research. Furthermore, allocation to the NINCDS of the funds authorized for clinical testing of orphan drugs would allow the Institute to increase its activities in this important area.

Question: What orphan drugs do you believe need more support than they presently are getting?

Answer: The following areas of orphan drug development are ready for further development.

1. Studies of the effects of mannitol and pentobarbital in ameliorating coma associated with Reye's Syndrome.

2. Studies of the use of phenobarbital in preventing intraventricular hemorrhage in premature, low birthweight infants.

3. Clinical testing of several new drugs for prevention of specific forms of epileptic seizures.

4. Clinical testing of drugs to improve therapy for movement disorders, such as Tourette's syndrome and Parkinson's disease.

PROTECTING THE INVESTMENT

Question: At a time when many budgets are going down, Congress has been increasing funding of the National Institutes of Health including your Institute. We are concerned that these scarce resources be carefully and effectively used and that there be no basis for criticism of your management of this money. What assurances can you give us that your Institute is making careful and effective use of the appropriations we provide you?

Answer: The strongest tool for assuring careful and effective use of resources is the peer review system. As a consequence of the strong support shown by the Congress for our programs, the current research opportunities are producing a continuing increase in grant applications. Consequently, we are funding only the most meritorious grant applications as judged by the peer reviewers. With respect to research contracts, each major program unit of the Institute utilizes advisory committees of non-government experts to evaluate and rank research and development concepts and ideas. Other groups of non-government experts then evaluate specific proposals to implement these ideas. In this way both concept and project are independently and rigorously reviewed. Our Intramural Research Activities are also reviewed by outside experts through our Board of Scientific Counselors. The Board provides impartial critiques of our direct research activities and advice on the most likely productive research areas and approaches.

Moreover, in response to the request of this Committee, we are awarding a contract for a study of the research opportunities and needs in the neurosciences and communicative sciences. The study, which will be completed this year, will delineate high priority research needs and opportunities and will further insure that we invest appropriations as effectively as possible.

Question: Aside from the peer review system, what institutional arrangements do you have that serve to deter waste, fraud or abuse in the handling of Federal funds?

Answer: The entire NINCDS staff is aware of the need to conserve funds and avoid any waste. Examples of the types of actions we are taking include:

Contracting Practices. Instead of hiring government personnel, we are contracting out specific assignments. This practice allows us to obtain uniquely qualified persons, perfectly matched to a particular assignment. We can schedule work more accurately and need not have someone on the government payroll when their skills aren't absolutely needed at the time. We have recently used contractors at the Office of Scientific and Health Reports, the Intramural Research Program, and the Office of Biometry and Field Studies.

Increased Automation. Savings also accrue from the adoption of computer systems throughout the NINCDS.

Contract and Grant Negotiation. The NINCDS is conducting much more intensive cost negotiations than ever before with contract and grant recipients.

Auditors from the NIH Division of Management Survey and Review (a separate unit) investigate any allegations of waste, fraud and abuse.

VENEZUELA AND BALTIMORE STUDIES

Question: Several years ago you initiated a study in Venezuela to study several large families with an unusually high incidence of Huntington's disease. What results are you getting from the study -- and have you identified anyone who inherited the Huntington's gene?

Answer: In June, 1982, the NINCDS requested a group of expert consultants to evaluate the Huntington's disease (HD) research project in Venezuela. Their report confirmed that this project continues to offer the best prospect of reaching two major goals: 1) developing a practical and definitive early diagnostic test through the discovery of the HD gene; and 2) identifying the actual defect in the gene and developing corrective or preventive treatments.

Over the course of three one-month field trips, 1981-1983, pedigree information has been compiled on over 2500 individuals and tissue samples obtained from over 574 persons. These tissues are available for investigators worldwide. Scientists at the NINCDS supported Huntington's Disease Center Without Walls in Boston are using recombinant DNA techniques to study these samples in their search for a marker for the HD gene. In addition, the superiority of these large pedigrees for genetic research make them of value for studying other genetic diseases.

Longitudinal, in-depth, clinical examinations have been performed on 230 HD patients and persons at risk leading to some important new insights on the natural history of the illness. A unique feature of the Venezuelan community is its high degree of intermarriage. Eighteen individuals in the study have both parents with confirmed Huntington's disease, giving them a 75% risk for

inheriting the illness, instead of the usual 50%. This project has demonstrated that having two genes for HD is either lethal at conception or else looks identical to having one gene. Biochemical investigations are now underway on the tissues of these special research subjects.

Question: What is the study costing?

Answer: The cost to NINCDS has been approximately $100,000 for each of the three years. This has included support for Venezuelan collaborators, special handling and storage of tissues, and field studies.

Question: Who is conducting it for you and how many people are working on it?

Answer: In its preliminary phase as a feasibility study, the project has been conducted by NINCDS staff in collaboration with U.S. and Venezuelan consultants. Approximately 20 people each year work on the project for a month or more. NINCDS' objective is to develop this project into an investigator initiated research grant, a goal which should be achieved shortly.

Question: What is being accomplished through your Huntington's Disease Project conducted at the Johns Hopkins University Hospital in Baltimore?

Answer: The Huntington's Disease Project at Johns Hopkins University Hospital in Baltimore is a clinical and basic research program project grant directed toward improving methods of treating the disease through a better understanding of clinical symptoms and their variability and also through an elucidation of the biochemical cause and progress of the disorder.

Question: Where is the money for this work coming from?

Answer: As an investigator-initiated program project grant, funds to support this work come from research project grant monies.

Question: Please provide some details.

Answer: In the clinical realm, the investigators are completing a total census of all HD families in Maryland. They have the most extensive data existing on behavioral symptomatology and HD, especially the close relationship of depression to HD in certain families. There appear to be clinical or possibly genetic subtypes of the illness, some with greater motor involvement and others with more pronounced mental disorders. Scientists at Hopkins are perfecting clinical assessment techniques through intensive neurological and behavioral evaluations, including swallowing, eye movements, and nutrition, and are studying issues of genetic counseling and ethics.

Positron emission tomography (PET) is being used on living HD patients to study receptors for important brain neurotransmitters, while a number of investigators are looking for biochemical abnormalities in post mortem brain tissue. Hopkins scientists remain in the forefront of research on animal models of HD, particularly using potent toxic chemicals to mimic the pattern of

brain cell death found in HD. A major component of their work is the relationship of HD to Alzheimer's disease and other dementias.

AUTISM

Question: We are most interested in the progress of your new Section on Autism and Behavioral Disorders. What are your plans for neurological research which the Committee cited as one important aspect of the section's work?

Answer: The NINCDS Autism and Behavioral Disorders Section will hold a workshop late in FY 1983 at which a panel of experts will agree to produce specific research definitions for the autistic spectrum. In FY 1983, a program announcement for research on autism and behavioral disorders is planned, emphasizing electrophysiology, neuroepidemiology, genetics, neuropathology, and the development of animal models with behavioral pathology comparable to autism.

Question: How much do you plan to spend on it in FY 1983 and in 1984?

Answer: Expenditures on neurological research relevant to autism are estimated to be $2.55 million for FY 1983 and $2.60 million for FY 1984.

Question: How much will go into language training?

Answer: It is estimated that expenditures for research on language in autism will be $390,000 in FY 1983 and $450,000 in FY 1984.

Questions Submitted by Senator William Proxmire

REDUCTION IN AVERAGE COSTS

Question: You have proposed a reduction in the number of new and renewal competing research grants from 469 in fiscal year 1983 to 394 in fiscal year 1984. How do you reconcile this reduction with the statement on page 229 of your justifications that "The average cost of competing research project grants will be reduced in order to provide the maximum number of new grants as a vehicle for introducing new ideas and methods to research"?

Answer: The original fiscal year 1984 budget did propose to fund 394 competing new and renewal research project grants which represented a reduction of 75 grants from fiscal year 1983. The 1984 revised budget request of 524 new and renewal research project grants is an increase of 55 competing grants over the 1983 level of 469.

In order to fund 524 competing new and renewal research project grants, a negotiated reduction in average costs is required on most competing and noncompeting grants in order to provide the $58,537,000 required. In addition, the reduction in average costs to provide for 524 competing grants results in 31 percent of approved grants being funded compared to 22 percent funded if only 369 grants were awarded. The reduction in average costs will permit the award of the proposed number of competing grants in order to

increase the opportunity for introducing new ideas and methods to biomedical research. Despite this reduction from the March projected average cost, we expect to make awards at an average cost for a 1983 award at $106,817 and for a 1984 award at $111,712.

NEUROLOGICAL DISORDERS OF EARLY LIFE

Question: Your Clinical Research Program is targeted for increased funding in fiscal year 1984 whereas Biological Basis Research is being cut in many areas. How can you justify, for example, a cut of $215,000 in the Biological Basis research on "Neurological disorders of early life" with an increase in the clinical program in this area of $275,000, since these research efforts are so interdependent?

Answer: The January budget for Biological Basis research on the neurological disorders of early life reflected a decrease of $215,000 from the 1983 level and an increase of $275,000 for the clinical program over the 1983 level; this is a net increase of $60,000 over 1983. The April budget provides for an increase of 130 competing research project grants and $12,800,000, resulting in a revision for the estimate for neurological disorders of early life. The new 1984 estimate for Biological Basis research is now $439,000 above the 1983 level and $355,000 above the 1983 level for the clinical program. This will result in a net increase of $794,000 over the 1983 level for research on neurological disorders of early life.

ALZHEIMER'S DISEASE

Question: How do your efforts relate to those of the Aging Institute with regard to research in Alzheimer's disease?

Answer: Since 1976, the growing interest in Alzheimer's disease has been promoted with research support from the NINCDS. Areas of specific attention have focused on neurochemical analysis of the Alzheimer's brain in an effort to understand the cause of the disease, and to follow its progression. The NINCDS research efforts complement and is actively coordinated with related research supported by the National Institute on Aging (NIA) and the National Institute of Mental Health (NIMH). In order to enhance coordination and communication between the several departmental organizations involved in Alzheimer's disease activities, Secretary Heckler has recently appointed a task force on Alzheimer's disease under Dr. Brandt's leadership to monitor all such activities and assure effective utilization of our resources.

Question: Is there needless duplication of effort here?

Answer: No sir, we are confident that there is not. NINCDS emphasis on the neuroscience and neurological aspects of this devastating disorder is enhanced by complementary research activities of the other Institutes.

STABILIZATION OF RESEARCH

Question. This Committee was instrumental several years ago in developmenting the policy of "Stabilization of Research" for NIH. Does that policy continue to serve us well?

Answer: The key element in current NIH program strategy is to assure a predictable level of support for investigator-initiated research project grants. This, if accomplished, would stabilize the single largest high-priority component of the research base. This policy will continue to serve us well as long as a proper balance among various mechanisms of support is maintained.

Question: What is its specific impact on NINCDS, given the tremendous research opportunities which are within our grasp in this area?

Answer: The highest priority continues to be the support of investigator-initiated research projects which historically have provided the biomedical knowledge base which leads to improved health. For FY 1984 we plan to fund 524 competing new and renewal research project grants, with concomitant reductions in other research support mechanisms. For the term, we must be careful not to disrupt overall program balance among research support mechanisms.

CLINICAL TRIALS

Question: I notice that you have not asked for funding for clinical trials. Does this mean that little benefit would follow from such trials?

Answer: Clinical trials are very important but first priority has to be given to the funding of investigator-initiated research projects of extraordinarily high scientific merit. When the budget was revised in April to provide funds for 130 additional competing research project grants, the new clinical trials proposed for 1984 had to be postponed.

Question: How about MS clinical trials?

Answer: One of the trials which is being postponed is on the treatment of multiple sclerosis (MS).

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

STATEMENT OF DR. RICHARD M. KRAUSE, DIRECTOR

ACCOMPANIED BY:

DR. JAMES B. WYNGAARDEN, DIRECTOR, NIH
DR. BERNARD TALBOT, DEPUTY DIRECTOR, NIAID
NORMAN D. MANSFIELD, DIRECTOR, DIVISION OF FINANCIAL MANAGEMENT, NIH
ANTHONY ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET, DHHS

BUDGET REQUEST

Senator WEICKER. Next, we will hear from the National Institute of Allergy and Infectious Diseases which conducts research on a number of very serious diseases such as flu, herpes, and hepatitis. Now, it is involved in work on a very deadly disease called Acquired Immune Deficiency Syndrome.

The revised budget request for the Allergy Institute is $289.4 million, or about $8 million more than the January budget and $15.8 million above the 1983 level.

Our chief witness is a very familiar face to this subcommittee—Dr. Richard M. Krause.

Dr. Krause, we welcome you back and are glad to have you here.

OPENING REMARKS

Dr. KRAUSE. Thank you very much.

Let me first introduce Dr. Talbot, the Deputy Director of the Institute.

May I make a few brief remarks?

Senator WEICKER. Go right ahead.

Dr. KRAUSE. First of all, let me say infectious disease has been part of the everyday experience of life. We all know that. And despite antibiotics and vaccines, about 20 percent of all patients who seek medical care do so because of infection.

Infections remain one of the most frequent causes of absenteeism from both the workplace and school. They circumnavigate the globe. Malaria, for example, is recurring in much of the world.

Within the last decade, we have seen new infections caused by previously unrecognized microbes.

Infections are more than just those that are handed down to us such as pneumonia and influenza. The new ones include Legionnaire's disease and Lyme arthritis which was mentioned previously. Lyme arthritis was first described in Connecticut, a little bit too close to my country home in North Stonington, I might say, and has since spread throughout Connecticut, throughout the Northeast, and throughout the north-

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ern tier of States as far West as the Dakotas. I had prepared that comment for Senator Andrews should he have been here.

NIAID scientists recently discovered the microbe that causes Lyme arthritis, and we can now treat it. It is not a trivial matter. In one small community in upstate New York, there were 150 cases just last summer. Now, we must learn how to prevent it.

Also we have the current epidemic of sexually transmitted diseases that began 10 or 15 years ago. In addition to syphilis and gonorrhea, 10 additional infections can now be added to the list of those sexually transmitted. And it appears also that acquired immune deficiency syndrome—AIDS—can be sexually transmitted.

We have yet to identify the microbe responsible for AIDS, which is probably a virus. When we do, we must learn how to treat and prevent it. These matters are under intensive research.

What is behind the emergence of these new infections—Legionnaire's, Lyme arthritis, and AIDS?

Microbes, like all living things, like you and me and all the rest of us, are swimming in the evolutionary stream. The influx of new microbes is programed in the genetic machinery of life.

There is, however, an ironic twist to the matter. Many new technologies, such as recombinant DNA and hybridomas, have sprung from research on microbes. And it is these new technologies that provide us the opportunities for their defeat.

Now, we are putting these new technologies to work and have outlined a program, called the accelerated development of new vaccines.

In the 100 years since Pasteur, we developed only 14 vaccines—in 100 years, 14 vaccines. With these new technologies I believe we can accelerate vaccine development and do as much in the next 10 years as was done in the last 100. I firmly believe that.

Now, a brief word about the immune system that defends us against infections.

Lewis Thomas has just written about medicine as the newest science. Well, the immune system is the newest system of the body to be recognized. So we have much work to do on it.

In gearing up for the assault on infectious agents, the regulatory mechanisms of the immune system increase or decrease the immunity on demand. Regulation of immunity is due to a delicate balance of the internal forces within the immune system which we can't go into here, but can look at it this way:

It operates much like the Federal Government with a system of checks and balances. Disturbances of these checks and balances result in diseases of the immune system, such as allergies and a large, diverse group of immune disorders, including lupus erythematosus, arthritis, multiple sclerosis; and perhaps even some forms of diabetes.

Now, remarkable progress has been made in the research on the immune system. And I recounted some of it in my opening statement. While it may be the newest system to be discovered, it is the one receiving the most intensive study.

Remarkable progress is being made on the specific problems of asthma and allergies. Let's not overlook asthma. There were two diseases which most of us who were physicians found difficult to treat because they were so intractable and so resistant to management. One was arthritis, the other, asthma. But recent discoveries offer the opportunity to treat both of these diseases.

There is a new class of substances that will become as familiar to you as the histamines. These new substances are called leukotrienes. They are released by the body during an allergic attack, causing inflammation. Because these substances are so toxic, we are looking for drugs to inhibit their effects.

We expect that these new antileukotriene drugs will be 100 times more effective than antihistamines controlling the symptoms of asthma and allergies.

In closing, I would like to just reiterate your theme, Mr. Chairman, on the importance of the out years. You put it much better than I can. The advances recounted here, not just by me, but by Dr. Wyngaarden and all of my colleagues, would have seemed like science fiction when I was in medical school 35 years ago or when you were in Yale.

This progress rests on the sure foundations of past research. What of the future? Goethe, the German poet and philosopher, said we must labor to possess what is inherited. Labor to possess what is inherited. In the decade ahead, I believe we must continue our labor if the science of today is to become the art of medicine tomorrow.

I would be happy to answer any of your questions.

ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

Senator WEICKER. Thank you very much.

I was interested, I must confess, to hear you quote Goethe. My grandfather came over from Germany, a graduate of the University of Heidelberg, to found one of the great pharmaceutical companies in this country.

Goethe and Schiller were the two men he quoted the most. So it was just a harking back to earlier days when I heard you mention him a minute ago.

Let's talk a minute about the area that I am sure is on many people's minds—an increasing number of persons afflicted with the AIDS syndrome. What role is your Institute playing in the search for the cause and possible cure?

I would really like to pull this together if I might in terms of what it is that your Institute is doing. Is there indeed further research going on in the other Institutes at NIH? What is going on in the private sector?

I would like to try to get possibly from you a comprehensive overview as to who is doing what on this problem and whether or not it is coordinated and whether or not enough resource is being put into it.

Dr. KRAUSE. Well, I might make one or two comments, but I think perhaps Dr. Wyngaarden might want to give an overview for the NIH as a whole.

Indeed, because so much is being done, Senator, it may be useful for us to supply a detailed narrative. We really have a tremendously diverse and extensive program on the cause of the disease, on the immunological abberations of the disease, on the complications that occur, such as the pneumonias and the other infections, including mycotic or fungal infections, and on the tumor-like growths that frequently develop.

All of this is receiving intensive investigation. We began those investigations in 1981 not only in various research programs around the country, but also at the Clinical Center itself.

RESEARCH COORDINATION ON AIDS

Let me give you an example of the cooperation that exists. In California, we have a large center for immunology research supported by us and the Cancer Institute. Some of the first research on this problem was there and continues to be done there.

Second, at the Clinical Center, we have patients under intensive treatment and investigation. That research is primarily being conducted by investigators of the Clinical Center, the National Institute of Allergy and Infectious Diseases, the National Cancer Institute, and the National Heart, Lung, and Blood Institute.

So I think that we have a major coordinated research effort within the NIH, and the Centers for Disease Control.

FUNDING OF AIDS

Funding for research efforts in NIAID in 1983 will be $4 million. We funded about $2 million already and will fund another $2 million between now and the end of September. In fiscal year 1984, we expect to fund at least $6 million or $2 million more than we are funding this year.

RESEARCH STRATEGY FOR AIDS

We will concentrate on the search for the infectious agent. Although we think it is most likely a virus, that path must be kept open; it may not be. It is the most likely possibility at the moment. But we are going to have to cast a wide net to be sure that whatever it is doesn't escape us.

Then, we must look very hard at what is wrong with the immune system and why this virus is able to attack the immune system just as influenza attacks our respiratory system. Why is it able to attack the immune system and prevent the immune system from thereafter warding off infections?

That is why these patients die. They die from overwhelming infection. And we must find out what that immune defect is and see if we can't find some way to reverse it. Because there are now over 1,300 patients, and there are probably going to be many, many more, we must find a way to treat those people already afflicted.

Finally, of course, we want to identify the agent so we can then devise appropriate means of prevention.

I think perhaps I should stop here if that answers your question as far as our Institute is concerned and let Dr. Wyngaarden speak for the NIH.

NUMBER OF CASES OF AIDS

Senator WEICKER. Let me ask one question. And I want to go to Dr. Wyngaarden, but let me ask, what are we talking about in numbers as far as this problem is concerned right now? And what is the progression?

Dr. KRAUSE. Well, at the moment, of course, it is going up almost exponentially, which means very rapidly. Over 1,300 cases have been reported since the first several were reported 3 years ago. The number of cases as reported by the Centers for Disease Control is now approaching 30 a week.

There are some estimates that in certain populations of New York and San Francisco as many as 10 percent may eventually come down with this disease.

Senator WEICKER. Ten percent, you mean certain populations?

Dr. KRAUSE. Certain segments of the homosexual community, for example. Not all, by any manner of means, but 10 percent of certain subsets of this population. So we may very well be seeing the tip of the iceberg, as far as the spread of this disease in the future is concerned.

One problem is that there is a latent period of 6 to 18 months between the time of sexual contact with a partner who has the disease before it occurs in the contact individual. So there could very well be a large number of people who have been exposed and who have yet to develop the illness.

HOW AIDS CAUSES MORTALITY

Senator WEICKER. But then, I gather what happens insofar as the mortality rate is concerned, the mortality is associated with another infection, right, which is produced by the lack of the immunizing system to operate.

Dr. KRAUSE. Let me straighten that out. When we talk about an infectious agent as the possible cause of AIDS, we are not talking about an agent which would be lethal in and of itself. What we think it does is to destroy the capacity of the immune system to ward off infections.

When that happens severe pneumonias and other infections such as those caused by fungi develop in these individuals. It is very difficult to treat because AIDS patients no longer have an effective immune barrier.

The final episode in these patients is usually an infectious disease that overwhelms the system. But these infections are not caused by the same virus that we suspect comes in and destroys the capacity of the immune system to defend against subsequent infections.

Senator WEICKER. Dr. Wyngaarden?

Dr. WYNGAARDEN. Yes; Dr. Krause has beautifully described the general situation and also that with respect to the Allergy and Infectious

Diseases Institute. It and the Cancer Institute provide the largest amounts of support for AIDS studies that are specifically ongoing.

The total NIH investment in 1983 is about $9.5 million. The total PHS is about $14 million. In fiscal year 1984, the NIH investment will be about $12.5 million and the total PHS nearly $17 million. That, as I mentioned earlier, is on top of a very large investment that has been going on for years in related conditions.

That is, studies of the particular lymphocytes that are affected in this condition, immunological studies of T-cells and B-cells for example, other studies of opportunistic infections and Kaposi's sarcoma. And about half a dozen centers throughout the country are devoted to the study of sexually transmitted diseases.

So there is a great deal of relevant work going on in addition to these highly focused studies that are being funded this year and next year.

And the answer to the questions that Dr. Krause summarized could come from any of these places. But we recognize this condition as a very serious one, not only to the populations that are affected—and there are several populations—but also because of the potential insights that may be gained from intensive study of this condition and may be relevant to cancer problems in general.

TRANSMISSION OF AIDS

Senator WEICKER. With regard to transmission, are you fairly certain how it is transmitted? Is it related, in other words, solely to oral sex or can it be transmitted in some other way?

Dr. KRAUSE. Those studies have been done, in large measure by the CDC, although now our research centers are working much more extensively on this matter. There is a good deal more to do on the epidemiology.

I think the most that one should say at this juncture is that transmission of the disease is the result of sexual contact. Whether it is due to one particular sexual activity or another, I don't think has been proven.

There are those studies suggesting that certain forms of sexual activity are risk factors, but I think we need more epidemiological research.

Senator WEICKER. This is sort of key, isn't it, to the transmission factor as to the magnitude of the problem you have on your hands?

Dr. KRAUSE. Yes, indeed.

Senator WEICKER. I guess, indeed, if it expands beyond the confines of the sexual activity, you have got a real problem there.

Dr. KRAUSE. That is why we give it such high priority. And I might say that the grants we are funding this year and next year for AIDS research will not be cut. We will fully fund those. We recognize the potential for AIDS to spread from the primarily homosexual population to the bisexual population, and from the bisexual population to the heterosexual population, because each of these populations merge at the margins, quite obviously. And then it will involve the larger population as a whole.

The epidemiology must be studied intensively; we are going to make every effort to do that. We have worked on it already, but we must double our efforts.

BUDGET FOR FISCAL YEAR 1984

Senator WEICKER. On the matter of the competing grants, what is the change in numbers insofar as your Institute is concerned?

Dr. KRAUSE. Well, under the January budget we had 318 competing grants, and 420 are reflected in the budget submitted within the last few days—we went up 102 grants from the January budget.

Senator WEICKER. And you have no research centers that are affected; is that correct?

Dr. KRAUSE. Well, we have a small research centers program. We have only two coming up for renewal this year. We have 20 centers funded at $5 million.

It is almost an embarrassment to call them centers. They are pieces of core money for important areas of asthma and allergy research and research in immunology.

Senator WEICKER. Now, what about the other areas that are being cut back—clinical trials?

Dr. KRAUSE. Our clinical trials have been essentially stationary, and have been a fairly small part of our budget. A planned clinical trial on a multivalent protein I gonococcal vaccine, included in the January budget, will be postponed.

Let me not speak about the current administration, but I have been here 7 years, 8 years—the time flies. When I came, the bulk of our resources were in research grants where I think, indeed, it is very important that they be.

On the other hand, you have heard discussed the importance of centers activity and clinical trials. Because of the importance of basic biomedical research, we have not, as an Institute, built up a strong portfolio in these areas.

It is traditional with the Institute and not something that is unique to this particular budget.

PURCHASE OF INTERFERON

Senator WEICKER. We note that $500,000, or almost one-half of your proposed increase of $1.1 million for direct operations, will go for the purchase of interferon.

Assuming that the Cancer Institute and other Institutes use interferon, to what extent does NIH buy it on a coordinated, mass basis that might produce economies of scale? Or is there no coordination?

Dr. KRAUSE. Well, there is actually, but there are also different kinds of interferon available. At the moment, we are all trying to get as much as we can. The Cancer Institute, for example, is using one kind of interferon from one supplier for their clinical trials, using it for AIDS, and we are using another brand of interferon from a different supplier. We are both trying to get all we can out of the market and into the patients.

We do, however, have interferon donated to us by the American Cancer Society.

PREPARED STATEMENT AND SUBMITTED QUESTIONS

Senator WEICKER. I have further questions for response to the record, Dr. Krause.

And it is a pleasure to have you before this committee. And I hope you will find a few days to go up to eastern Connecticut.

Dr. KRAUSE. I look forward to it if the Gypsy Moths don't get us again.

[The information follows:]

Statement of Dr. Richard M. Krause

Infectious diseases are now and always have been part of everyday life. For generations they were accepted as inevitable as death and taxes. In fact, calamities, such as the plague in the 14th century and tuberculosis in the 19th, so influenced the course of human events that a new subspecialty of history is being devoted to the influence of disease.

We exist on this globe in a sea of microbes. While most of these microbes are usually harmless, many others are deadly. Beginning about a century ago, individual microbes, one by one in rapid succession, were identified as the cause of a variety of infections. Then, following decades of difficult and tedious research, scientists developed antibiotics and vaccines to treat and prevent many of the common infections. Despite this progress, infections as a group remain the single most common cause of morbidity in the United States and the most common cause of mortality in the world at large.

The problems of prevention and treatment of infections are complex; the solutions, elusive. There are several reasons why this is so. For example, there are at least 500 different microbes of all sorts--bacteria, viruses, parasites, and fungi--that cause infectious diseases. With increasing frequency, infectious agents emerge as causes of new diseases, such as Legionnaire's disease and Lyme arthritis. In addition, the diversity of viruses has frustrated efforts to control them. Hundreds of different viruses can cause diseases as uniquely different as the common cold, genital herpes, encephalitis, and hepatitis, to name just a few. And yet, despite decades of research, there are only nine successful vaccines currently employed to prevent viral infections. And while several antiviral drugs can be used for very specific purposes, there is no drug as effective against viral infections as penicillin has been in treating a variety of bacterial infections.

Despite the obstacles, we continue to make advances in the struggle against infections. Let me recount a recent success in the development of drugs to treat genital herpes, an infection that is now epidemic. Just recently, at the NIH Warren G. Magnuson Clinical Center we found that the antiviral drug acyclovir, taken orally, prevented frequent recurrences of severe genital herpes. While it is too early to recommend this treatment for general use, we are optimistic that similar drugs will prove even more effective in the treatment of this disease, until the time it can be prevented by a vaccine--a vaccine that may be made possible by genetic engineering.

Herpes, flu, hepatitis--these are among the health problems we hear mentioned most often. And yet there are other important, but less obvious, reasons why infections still require our close attention. Infections are among the most severe complications in patients with cancer, as well as in patients with other chronic diseases such as rheumatoid arthritis and systemic lupus erythematosus. Frequently, this occurs because the drugs used to treat these diseases can cripple the body's defenses against microbial invaders. Also, in the search for causes of these diseases there is a nagging suspicion that infections may, in some indirect way at least, be responsible. In animals, certain forms

of cancer and arthritis are clearly associated with specialized infections. Thus, we must reexamine the possibility that unknown infectious agents may also cause chronic diseases in man. This will require new initiatives and the recognition by young scientists currently selecting a research career that infectious diseases still constitute an exciting challenge.

The immune system stands between us and the danger of attack by microbes. "The watch on the ramparts," I call this defensive role. When an attack succeeds in breaching the ramparts and produces an infection, the immune system mobilizes a vast reservoir of strength. But even when successful, this counterattack might take days, even weeks; as a consequence, infections may last only a few days or persist for several weeks. Vaccines can be used to prevent infections by stimulating the immune system to constant vigilance. Thus, recognizing that prevention is the most cost-effective way to control disease, we have launched a program to accelerate the development of new vaccines to prevent gonorrhea, genital herpes, meningitis, hepatitis, and malaria. Included also is a vaccine to prevent pseudomonas infections, which are common in patients with cystic fibrosis and severe burns.

While the benefits of immunity are clear, we now know that the immune system has a dark side, a side where danger lurks. Disorders of the immune system are now known to be common occurrences and responsible for a variety of diseases. Among these are asthma and allergy, diseases in which an aberration of the immune system causes a reaction after exposure to common substances such as plant pollens and insect venoms, as well as industrial products.

In addition to allergies, there is another large and diverse group of immune system disorders called autoimmune diseases. These, I call "the revolt from within." Let me explain why. Immune defenses that are usually marshalled against invaders can, for reasons still largely obscure, turn against the body itself. Some factor triggers the immune system to produce antibodies that attack, injure, and, in some cases, even destroy the body's tissues and organs. These antibodies are called autoantibodies, and the pathologic process they produce is called autoimmunity. There is accumulating evidence that autoantibodies ignite inflammation, leading to destruction of vital organs. Autoimmunity is associated with diseases such as systemic lupus erythematosus, rheumatoid arthritis, multiple sclerosis, myasthenia gravis, hemolytic anemia, and some forms of diabetes.

What causes the revolt from within? This remains a mystery, although in animals there are autoimmune diseases triggered by virus infections. Presumably, cellular changes initiated by the virus set the stage for the production of deleterious autoantibodies. So the search is on to define this relationship between infectious agents and the immune system, and to identify viruses or other agents that cause autoimmune diseases in man.

Historically, the study of immunity began with identifying the chemical components of the bacteria and viruses that stimulate antibody production. These substances are called antigens. But for many years we had only fragmentary knowledge of the immune system itself. There was confusion because the immune system and its aggregation of organs--the thymus, spleen, lymph nodes, and

bone marrow--seemed to lack an orderly arrangement within the body. In appearance, it was certainly not as neatly crafted as the filtration plant of the kidney, for example. However, in the last decade immunologists have been probing the mysteries of the immune system and already the shadows fade.

I would like to share some of the knowledge we have uncovered, most particularly about the several important mechanisms that regulate immunity. In gearing up for the assault by infectious agents, regulatory mechanisms of the immune system can increase or decrease immunity on demand. An explanation of these mechanisms begins with a discussion of the lymphocyte, one of the most important cells of the immune system.

The immune system contains one trillion lymphocytes. These cells play a key role in the regulatory processes that govern the production of immunity. Lymphocytes are of two major types: B lymphocytes and T lymphocytes. Through a complicated process, B lymphocytes, when stimulated by exposure to antigen, such as bacteria or allergic substances, multiply and produce special kinds of antibodies to attack the microbial invader. But what regulates the amount of antibody produced by B lymphocytes?

Regulation of immunity is the job of the second type of lymphocyte, the T cell. These cells supervise the B lymphocytes, controlling the magnitude of the immune response. There are two sorts of specialized T cells: "helper" T lymphocytes and "suppressor" T lymphocytes. Helpers are essential for B lymphocytes to produce antibodies in time of need, while suppressors restrain antibody production when danger passes. In short, the immune system is a finely tuned system of checks and balances.

As I described earlier, in persons with immunologic diseases the immune system produces the abnormal antibodies that trigger the disease process. We now know that these antibodies occur because there is an imbalance between the helper and suppressor T cells. It's as if there were a disturbance in the checks and balances that regulate immunity.

The imbalance between helper and suppressor T cells in the blood of patients can now be detected by a new computerized instrument called the fluorescence-activated cell sorter (FACS). This has been one of the most important recent advances in clinical immunology, because this instrument can be used to examine the T cell abnormalities in many immunologic diseases. For example, suppressor T cell deficiency is detected in the blood of patients with lupus, multiple sclerosis, severe allergic eczema, and some hemolytic anemias, while helper T cell deficiency is found in some forms of cancer as well as in a disease receiving much attention these days, acquired immunodeficiency syndrome, or AIDS. Blood tests using this sophisticated instrument make possible more effective diagnosis and treatment for these patients.

One of the most mystifying events in medicine is the occurrence of defects in the protective ramparts of the immune system. As a consequence, the body is invaded by multiple infections and even cancer. This phenomenon has taken on a special urgency with the current epidemic of AIDS, a disease in which the protective walls have crumbled and fatal infections have moved in. The cause of this new disease is unknown, although there is reason to believe that

some unidentified microbe is responsible for the immune defects in AIDS. These patients usually develop either severe secondary infections, including a rare form of pneumonia, or an unusual skin cancer called Kaposi's sarcoma, or both.

The common denominator of AIDS is a severe and apparently irreversible suppression of the immune system leading to death by infections or cancer. By using the FACS instrument I mentioned earlier, investigators have found that this immune deficiency is caused by a marked decrease in helper T cells in the blood. An understanding of these abnormalities in the ailing immune system will be essential if we are to correct the defect by new forms of treatment.

I am optimistic that through research we will discover the cause of this alarming disease and learn to treat and prevent it. Such optimism stems, in part, from our recent success in unraveling the mystery of Lyme arthritis. For nearly 10 years we had known that this disease occurs in the northern tier of states; scientists later observed that the disease developed following a tick bite. But the cause remained unknown despite an intensive search. Recently NIAID scientists have shown beyond question that this disease is transferred from animals to man by ticks, and that the infectious agent is a previously unrecognized bacterium. This disease can be cured with penicillin, but, more importantly, discovery of the cause will open up new avenues for prevention.

In the past few years I have reported to you in considerable detail the research programs in asthma and allergic diseases; this year my remarks will be brief. Investigators have found a new class of toxic substances, called leuko-trienes, that are released by the body during an allergic attack. These substances have been identified as a major cause of inflammation during allergic reactions. Human studies have shown, for the first time, that leukotrienes play a role in asthma. These substances reduce the diameter of the small airways of the lungs, restricting the passage of air and creating the "struggle for air" so characteristic of patients with asthma. A search for specific drugs to inhibit the toxic effects of leukotrienes is being actively pursued. As a matter of interest, I should mention that one of the 1982 Nobel prizes was awarded to a pioneer in leukotriene research. In addition to this promising avenue of investigation, we are continuing to find additional ways to improve the effectiveness of immune therapy [allergy shots] for allergic diseases.

In closing let me add this concerning the merits of basic research: We have inherited from the past century a legacy of new concepts, new tools, and new knowledge for the treatment and prevention of disease. In these few minutes I have recounted advances that would have seemed like science fiction 35 years ago when I was in medical school. These advances rest on the sure foundations of past research. And what of the future? Goethe, the German philosopher, said we must labor to possess what is inherited. And so, we must continue our labor if the science of today is to become the art of medicine tomorrow.

This concludes my prepared statement. The budget request for FY 1984 is $289,428,000. I would be pleased to answer any questions.

Biography of Dr. Richard M. Krause

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Birthdate: January 4, 1925 - Marietta, Ohio, U.S.A.

Education: Marietta College - B.A. 1947
Case Western University School of Medicine - M.D. 1952

Academic Appointments:

1975 to present	Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, Md.
1968 - 1975	Professor, Rockefeller University and Senior Physician to the Hospital, New York.
1966 - 1968	Associate Professor, Rockefeller University, and Physician to the Hospital, New York.
1965 - 1966	Professor of Epidemiology and Professor of Medicine, Washington University School of Medicine, St. Louis, Missouri.
1962 - 1965	Professor of Epidemiology and Associate Professor of Medicine, Washington University School of Medicine, St. Louis, Missouri.
1961 - 1962	Associate Professor, Rockefeller Institute, and Associate Physician to the Hospital, New York.
1957 - 1961	Assistant Professor, Rockefeller Institute, and Associate Physician to the Hospital, New York.
1954 - 1957	Assistant, Rockefeller Institute, and Assistant Resident Physician to the Hospital, New York.
1953 - 1954	Assistant Resident, Ward Medical Service, Barnes Hospital, St. Louis, Missouri
1952 - 1953	Intern, Ward Medical Service, Barnes Hospital, St. Louis, Missouri
1950 - 1951	Research Fellow, Depart. of Preventive Medicine, Case Western Univ. School of Medicine, Cleveland, Ohio.

Commissioned Corps, USPHS

1977 to present	Assistant Surgeon General
1975 - 1977	Surgeon

Societies and Organizations:

American Academy of Allergy
American Academy of Microbiology
American Association for the Advancement of Science
American Association of Immunologists
American College of Allergists
American Epidemiological Society
American Rheumatism Association
American Society of Biological Chemists
American Society of Clinical Investigation
American Society for Microbiology
American Thoracic Society
American Venereal Diseases Society
Association of American Physicians
Harvey Society
Infectious Diseases Society of America
Institute of Medicine, National Academy of Sciences
National Academy of Sciences of the United States of America
New England Society of Allergy
Practitioner's Society of New York
Royal Society of Medicine
Sigma Xi
Washington Academy of Medicine

Awards and Honors:

1982	Honorary Doctor of Science Degree, The Hahnemann Medical College and Hospital of Philadelphia
1982	Honorary Doctor of Laws Degree, Thomas Jefferson University, Philadelphia, Pennsylvania
1982	Distinguished Alumnus of the Year Award, Case Western Reserve University School of Medicine, Cleveland, Ohio
1982	Fellow, American Association for the Advancement of Science
1981	Honorary Doctor of Science Degree, Medical College of Ohio, Toledo, Ohio
1981	C. William O'Neal Distinguished American Service Award, Marietta, Ohio
1980	Republic of Egypt Order of Gumhuria Award
1979	Honorary Doctor of Science Degree, Rochester, New York
1979	DHEW, Distinguished Service Medal
1978	Honorary Doctor of Science Degree, Marietta College, Ohio

Clubs: Century Association, New York City, New York
Cosmos Club, Washington, D.C.

Editorships:

1976 - 1978	Editorial Board, Clinical Immunology and Immunopathology

Editorships cont'd:

1976	Advisory Editor, Journal of Experimental Medicine
1974 - 1975	Section Editor, Viral and Microbial Immunology, Journal of Immunology
1973 - 1975	Editor, Journal of Experimental Medicine
1973	Editorial Board, Immunochemistry
1970 - 1978	Editorial Board, Infection and Immunity
1969 - 1973	Editorial Board, Bacteriology Reviews
1963 - 1971	Associate Editor, Journal of Immunology

Other Appointments:

1982 - 1985	Member, Scientific Advisory Committee of the Max-Planck Institute for Immunobiology in Freiburg
1982 - 1985	Member, Membership Committee, Institute of Medicine, NAS
1980 - 1983	Chairman, Section 43, Microbiology and Immunology, U.S. National Academy of Sciences
1979 -	Trustee, Marietta College, Marietta, Ohio
1978	Member, Steering Committee of the Biomedical Sciences Scientific Working Group, World Health Organization
1977	The Albert Lasker Medical Research Awards Jury
1977 - 1977	Member, Board of Directors, Lupus Foundation of America
1976 - 1977	Member, Board of Directors, Asthma & Allergy Foundation of America
1973 - 1975	Directors Council, New York Heart Association
1973 - 1975	Treasurer, Royal Society of Medicine Foundation, Inc.
1971 - 1977	Board of Directors, Royal Society of Medicine Foundation, Inc.
1970 - 1974	Member, Infectious Disease Advisory Committee, National Institute of Allergy and Infectious Diseases, National Institutes of Health
1969 - 1971	Chairman, Advisory Council on Research, New York Heart Association
1968 - 1972	Deputy Director, Commission on Streptococcal and Staphylococcal Diseases, United States Armed Forces Epidemiological Board
1967 -	Consultant and Member, Coccal Expert Committee, World Health Organization
1967 - 1973	Board of Directors, New York Heart Association
1966 - 1970	Member, Policy Committee, American Heart Association
1966 - 1970	Chairman, Allergy and Immunology Study Section, NIH
1963 - 1972	Member, Commission on Streptococcal and Staphylococcal Diseases, United States Armed Forces Epidemiological Board
1963 - 1966	Member, Research Committee, American Heart Association
1963 - 1966	Chairman, Research Study Committee, Council on Rheumatic Fever & Congenital Heart Disease, American Heart Association

Questions Submitted by the Subcommittee

NEW BUDGET FOR FY 1984

Question: We would like to get your perspective on how the revised NIH budget for FY 1984 affects your Institute. How many additional new and competing grants will you get above the January Budget?

Answer: We would support 102 additional new and competing renewal research project grants over the January budget.

Question: And what further research will you be able to do as a result?

Answer: Funding these additional research project grants means that more free-ranging basic research in asthma and allergic diseases and major important infectious disease problems such as herpes and other sexually transmitted diseases, from which so many discoveries derive, will be conducted through the support of additional high priority investigator-initiated research project grants. Also, four more high priority multidisciplinary program projects in microbiology and immunology will be supported.

Question: It is our understanding that the January and April budgets both assume cuts in the average award for new and competing grants below what the full average cost would be. For new grants this appears to be a difference of some $17,800 ($142,400 full cost vs. $124,600 in revised budget). How will this affect your Institute?

Answer: The January and April budgets do assume cuts in the average award for new and competing research grants from the NIH computer model's projections of study section recommendations for 1984. However, the amount budgeted for new and competing research project grants in the April budget still includes an increase in the average cost of these awards over the 1983 average cost. Even when this increase is offset by the proposed reduction in indirect costs from 1983 to 1984, the 1984 average cost increases by about 5% over the 1983 average cost. The average cost reduction from the computer model's projected study section recommendations for our competing research project grants under the current plan is 8.5% in direct costs and 10% in indirect costs. This will require careful review by program staff in order to determine which grants or particular areas of research can withstand greater reductions than others. We hope our grantees will share in this effort to cut costs in ways that will be the least disruptive to their research programs.

Question: And to what extent will it start changing the scope and quality of the projects that are reviewed by your study sections?

Answer: The reduction in the average size of competing grants should not affect the quality of the projects that are reviewed by our study sections since the grants are reviewed before any proposed reductions are imposed. After review of the projects by the study sections, reduced funding by NIAID resulting in a decrease in the size of the grant means that the investigator must make very hard choices about following new leads and opportunities.

Question: Under your budget revision, the average NIH non-competing grant award is projected to decrease by about $12,400 below what the full average cost would be ($143,100 full cost vs. $130,700 in budget revision). How will this affect your Institute?

Answer: Even with this reduction the 1984 budget still includes an increase in the average cost of noncompeting awards of about 6%, offset by the 3% indirect cost reduction. The average cost reduction from the study section recommendations for our noncompeting research project grants under the current plan is 7.0% in direct costs and 10% in indirect costs. As with competing research project grants, described above, a careful review by program staff will be conducted to determine which grants or particular areas of research can withstand greater reductions than others. We hope that our noncompeting research project grantees will find ways to cut costs that will cause the least disruption to their research programs.

Question: And to what extent will it change the scope and quality of the projects that are reviewed by your study sections?

Answer: The study sections have previously reviewed our noncompeting research project grants. The average project period for NIAID grants is about three years. Thus, scientific peer review is undertaken at the time the grant must recompete.

Question: The Administration proposes to make cuts from the January budget in grants to specialized and comprehensive research centers. How does this affect your program?

Answer: Since our centers constitute less than 2% of our budget and are minimally funded at present, they will be reduced essentially by the 10% cut in indirect costs.

Question: And what will it do to research at those centers?

Answer: At their "bare bones" level, any cut in the centers will have impact; but we expect no serious adverse effects on the laboratory and clinical research.

Question: To what extent will any clinical trials be affected by the proposed cuts in research and development contracts and cooperative clinical research?

Answer: The proposed cuts in research and development contracts will require postponement of the planned clinical trial on a multivalent protein I gonococcal vaccine. This clinical trial was included in the January budget but has been deleted under the current plan.

Question: The new budget proposes to eliminate the 5% stipend increase for predoctoral and post-doctoral training, to make further reductions from the January budget in the number of trainees, and to decrease the number of research career awards to promising scientists. What effect will these steps have on your Institute's training program?

Answer: Although the current plan proposes to eliminate the 5% stipend increase, reductions in the number of trainees below the January budget are not contemplated in NIAID's support of National

Research Service Awards. The 5% stipend increase authorized for trainees and fellows in FY 1983 actually resulted in a net increase to the individual of $50 to $60 per month, on the average. It is encouraging to note the results of a recent study of medical school seniors. These young people are motivated toward research careers more by the opportunity to search for new knowledge than by financial rewards. The elimination of the stipend increase is consistent with other Administration proposals, such as not allowing a cost-of-living increase for Federal workers and delaying planned cost-of-living increases for Social Security recipients. Nevertheless, the change in stipend may influence the young to seek opportunities in medical practice or, indeed, early on in their careers, in fields other than medicine such as business administration.

The current plan reflects a reduction of six competing research career awards from the January budget.

Question: And what effect will it have on young people contemplating careers in biomedical research?

Answer: Students contemplating a research career often will consider the marketplace before embarking on the long-term commitment required by biomedical research. There must be convincing prospects for continuing support, growth and advancement. In addition, research career awards are critical to attracting and providing career tracks for young scientists, particularly M.D.'s.

Question: To what extent will the proposals to reduce funding for General Clinical Research Centers and Biomedical Research Support Grants affect biomedical research in general and your Institute's work in particular?

Answer: The proposals to reduce funding for the General Clinical Research Center (GCRC) and the Biomedical Research Support (BRS) grants were two reductions necessitated by the decision to fund 5,000 new and competing renewal research project grants within the same total dollar level as in the January budget.

The proposal to reduce the funding for GCRC awards by $2,021,000 would enable the Division of Research Resources to maintain funding for all 74 of the existing centers, although at a reduced level, by careful negotiation of each Center award. As a result, there would be some reduction in the core support that the Centers provide to investigators working on NIH supported research project grants. In 1982 the GCRC provided the important clinical research environment for clinical investigators who hold a portfolio of 1,298 NIH-supported research grants valued in excess of $200 million.

The work of the NIAID would be affected by the proposed reduction in GCRC funding. In 1982 more than 106 NIAID supported clinical research grants costing over $14 million relied upon the trained staff, research beds, equipment and clinical environment provided by the GCRC to carry out research efforts on patients with severe asthma and allergies, and immunologic diseases such as arthritis, lupus and multiple sclerosis.

The Biomedical Research Support grant program awards funds to research institutions based on their level of PHS research grant

support. These funds complement or supplement project grants by providing for pilot research, support of new investigators, centrally shared instrumentation, interim support and emergency funding. In 1982, BRS grant funds were used to support nearly 9,000 such research activities in 516 grantee institutions. The proposed reduction in the BRS grant activity of $24,657,000 would result in 52% reduction in the average size of all BRS awards. As such, 52% of research activities at the institutional level that are currently supported by BRS grant awards would have to find other sources of funding.

The work of the NIAID would be affected by the proposed reduction in BRS funding. In 1982 more than 251 NIAID supported research grants costing over $24 million were awarded to institutions which also relied upon the flexible funding provided by the BRS grant award mechanism to supplement or complement their research efforts. New instrumentation and electronics is very expensive, and centrally shared equipment is one way to be certain that many investigators at a university have access to the latest technical advances.

The availability of institutional resources and specialized facilities provided by GCRC and BRS grants are vital to the ongoing program of studies being undertaken by several of our Allergic Disease Centers. Several groups are working on the problem of determining which chemical mediators cause asthma. In order to accomplish these studies, clinical research beds must be available so that patients can undergo hospital procedures such as bronchoscopy and bronchoalveolar lavage which allow for direct procurement of study materials from the lungs. Studies to document food allergies under controlled conditions and direct observation also require patient hospitalization. Clinical challenge studies in insect sting allergic patients that contribute information on diagnosis and efficacy of therapy provide another example of research dependent on access to hospital research beds.

ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

Question: The nation is becoming aware of the increasing number of persons afflicted with Acquired Immune Deficiency Syndrome (AIDS) which carries an extremely high mortality rate. What role are you playing in the search for the cause and possible cure for this terrible disease?

Answer: Intramural and extramural scientists have from the very beginning of the outbreak been looking for an infectious agent as the cause, and research also has been concerned with the nature of the immune deficiency. Finally, many different approaches have been tried to treat the immunodeficiency as well as the life-threatening secondary infections. The NIAID recently held a workshop to discuss strategies for detecting viruses or other infectious agents which may be causing AIDS. Participants were experts in the field of viral infectious diseases who have had experience in identifying new infectious agents including some of the viruses which are commonly seen in AIDS patients. The conferees were in general agreement that the broadest range of virological diagnostic techniques be utilized in order to insure the best possibility for finding the causative agent in AIDS.

Question: And how much funding are you investing in the effort?

Answer: Total funding for AIDS research projected for FY 1983 is $4,050,000. This includes about $1,000,000 for support of projects received in response to a FY 1983 Request for Applications (RFA) to study AIDS. In addition to ongoing efforts the NIAID and NCI jointly issued another RFA for identifying the etiological agent in AIDS. NIAID will set aside $1,000,000 in FY 1984 for support of meritorious research applications received in response to this RFA. Currently, research projects in the intramural program are underway to identify the causative agent. These projects include taking serum and other body fluids from AIDS patients and injecting them into chimpanzees. The additional estimated investment of $2,000,000 under the President's request will bring total funding for AIDS research in FY 1984 to about $6,050,000.

Question: To what extent do you coordinate your efforts with the Cancer Institute and Centers for Disease Control?

Answer: The NIAID has worked closely with the NCI and CDC. The CDC is primarily responsible for surveillance of diseases and in this respect, CDC officials have been invited to participate in NIAID workshops and planning conferences on AIDS. NIAID officials meet frequently with CDC staff. The CDC data on AIDS have been extremely useful in all of the conferences and research planning for AIDS. In FY 1983, the NIAID has shared with the NCI the funding of meritorious research applications that were received after issuance of the RFA to study AIDS. As stated above, the NIAID and NCI are jointly sponsoring another RFA for research to identify the infectious agent in AIDS patients. Approved research applications received from this RFA will be funded in FY 1984. Also, Intramural researchers at the NCI and NIAID collaborate in clinical studies and treatment of AIDS patients.

Question: Does your research extend to possible cures for the observed failure of the immune system in AIDS victims--or are your looking mainly at treatments for the infectious diseases to which the victims become susceptible?

Answer: Research on diseases of the immune system is very much the mission of the NIAID. AIDS studies include both research on the particular defects of immune function in these patients as well as improved treatment and prevention of the infectious diseases common in the AIDS patients. NIAID scientists are investigating the imbalance in the T-lymphocytes seen in AIDS and studying other abnormalities of the immune system such as the high level of circulating immune complexes and increased amounts of antibodies. The NIAID also supports research on Pneumocystis carinii and cryptosporidiosis which are common infections frequently fatal to the AIDS patient. Special treatment studies are under way to correct the immune defect in AIDS. These include treatment with interferon, antiviral drugs, and bone marrow transplantation.

Question: Your justification indicates that the susceptibility to secondary infections may be the result of a "reduction of helper T cell population" in AIDS victims. How significant is this finding and how will it be used in the attack on this disease?

Answer: One of the diagnostic criteria for AIDS is the disproportionate balance between the helper and suppressor lymphocytes. In the AIDS patient, the helper cells are greatly diminished while the normal patient exhibits a ratio of helpers to suppressors of 2 to 1. Certain common viral infections can cause a depression of helper cells, but the condition is reversible; in the AIDS patient, no recovery of the helper cells has been observed. The meaning or the cause of the suppression phenomenon is not known; but, as it is not reversible in AIDS, information on the mechanism of suppression could lead to the understanding and possible treatment of T-cell imbalance. Recovery from immune system suppression should enable the body to fight opportunistic infections so these studies in helper cells are of critical importance.

SEXUALLY TRANSMITTED DISEASES

Question: You concede that gonorrhea is "still epidemic" and that genital herpes is in the same category. What hope do you have for developing a vaccine to deal with gonorrhea?

Answer: Gonococcal vaccine research is dependent on the basic research conducted by the NIAID over the past fifteen years. Recent developments suggest that an experimental vaccine can prevent infection of humans. This initial lead encourages us to press on with the development of what we hope will be a successful vaccine. The institute supports a number of investigators who are studying different aspects of the disease and the causal organism; these studies are all relevant to the development of a vaccine for gonorrhea. In Seattle, an investigator is making progress on development of a vaccine material (protein I) obtained from the outer membrane of the gonococcus. This material has been tested in human volunteers and shown to be safe and antigenic (stimulates production of antibody).

Additionally, the NIAID will shortly undertake, in its own intramural clinical laboratory, a trial in male volunteers to determine the efficacy of an experimental protein I vaccine in preventing or modifying the initial gonococcal infection in the male.

Question: And will we ever be able to bring the incidence of this disease down?

Answer: Bringing down the incidence of gonorrhea is a complex problem involving human behavior as well as purely medical and health related issues. Greater educational efforts directed toward the groups at highest risk (the sexually active younger elements of our population) as well as increased efforts in control (case finding and better therapy) would also have a significant effect on lowering the disease rate. If and when an effective vaccine for gonorrhea is available, it is predicted that appropriate use of this vaccine would be a significant factor in helping to control or to overcome the current epidemic of gonorrheal disease. The nation will also have to resolve the difficult social problems involved in distribution and use of such a vaccine on a large scale if the vaccine were to be truly effective.

Question: What progress are you making in the effort to find a cure or treatment for genital herpes?

Answer: Several new antiviral drugs have been announced that show promise of greater efficacy against herpes infection than thus far demonstrated for acyclovir and ara-A, two antiviral agents in use today. Two new drugs have been tested in mice and one has been described as "the most potent and effective drug known to date" against the disease. In animal tests, pretreatment with another drug protected 90 percent against infection, a result not reported with other antiviral drugs.

A consortium of U.S. scientists, most of whom receive grant support from NIAID, have designed and developed several new attenuated herpes simplex viruses (HSV) through recombinant DNA technologies. These attenuated viruses are being evaluated as candidate vaccines for protection against both type 1 (oral facial) and type 2 (genital) infections. Preliminary evaluation in animals indicate these vaccine candidates are safe and may prevent establishment of latent infections by fully virulent virus.

A killed vaccine for HSV is now undergoing clinical trials for efficacy against recurrent genital herpes in adults. This vaccine is produced by Merck, Sharpe & Dohme, Inc. Results of the trial will be available later this year.

The recent development of rapid diagnostic techniques coupled with effective therapeutic drugs and vaccines have the promise of powerful new controls for herpes infections in the foreseeable future.

Question: To what extent has the drug acyclovir been effective in dealing with genital herpes?

Answer: Acyclovir, when applied as an ointment, reduces the duration of the lesions and the duration of the time the patient is infectious for other individuals. Intramural NIAID scientists have recently completed a very encouraging study that indicates that oral acyclovir is beneficial in patients who have severe recurrent bouts of the disease.

The use of acyclovir for treatment of genital herpes infections represents the first drug regimen that effectively ameliorates some of the signs and symptoms of the infection. It should be emphasized, however, that drug therapy does not "cure" the disease, but does relieve the long period of discomfort in patients.

Acyclovir represents a first step in developing specific antiviral therapy for genital herpes infections. Efforts are continuing in investigating different formulations of acyclovir (route of administration, dosage) and other effective drugs.

PURCHASE OF INTERFERON

Question: We note that $500,000 or almost half of your proposed increase of $1.1 million for direct operations will go for the purchase of interferon. From whom do you buy the interferon and is this human or synthetically produced interferon?

Answer: Purchase of interferon for clinical trials prior to 1981 was a fairly simple undertaking. Up until that time, only two types suitable for administration to humans were available--

leucocyte interferon and fibroblast interferon. Most clinical trials supported by the NIAID utilized these two types of interferons. Because of the quantities required for clinical trials, sources for the drug were extremely limited. Interferon of standardized quality was purchased from the main source that was available, primarily the Finnish Red Cross.

In the late 1970's, the National Cancer Institute initiated efforts to investigate the role of interferons in the treatment of certain types of cancer. The demand created by the NCI stimulated production of interferons by numerous private organizations. Additionally, the rapid emergence of recombinant DNA technology provided the impetus for investigations of the molecular properties of the drug. These studies led to the discovery of the heterogeneous nature of interferon and culminated in the production of cloned human interferon in bacteria. We now have available natural polyvalent leucocyte or , fibroblast or , and immune or , as well as cloned varieties of interferon. A number of clinical trials are now underway with these products.

Question: Do you ask for bids on the purchase--or is this a sole source transaction?

Answer: The type of interferons to be purchased this fiscal year depends on the type of clinical trial to be undertaken. Preliminary assessment studies may be conducted with various types of interferons for various infectious diseases. Once a determination is made that a particular type of interferon will be used for a large clinical trial, sufficient quantities are purchased for the trial from a single provider. The particular source is determined by a low bid process. In some cases the institution performing the trial is authorized to purchase the interferon. For example, the Children's Hospital Medical Center, Boston, is performing, under NIAID contract, a trial entitled, "Treatment of Juvenile Laryngeal Papilloma with Interferon." For this trial the contractor procured the human leucocyte interferon from the New York Blood Center.

Question: Assuming that the Cancer Institute and other Institutes use interferon, to what extent does NIH buy it on a coordinated, mass basis that might produce economies of scale--or is there no coordination?

Answer: The NIAID and NCI continually collaborate through exchange of information and resources wherever possible. As more information becomes available on the recombinant DNA produced interferon and better production methods are developed, it is expected that prices will decrease. Prices for interferons produced from tissue culture of human peripheral blood (leucocyte), fibroblast, and lymphoblastoid cells have decreased as demand has expanded. For leucocyte interferon in particular, supply is limited because of the requirement for very large numbers of blood donors. Efforts are continually coordinated so that demand does not outstrip supply.

PROTECTING THE INVESTMENT

Question: At a time when many budgets are going down, Congress has been increasing funding of the National Institutes of Health, including your Institute. We are concerned that these

scarce resources be carefully and effectively used and that there be no basis for criticism of your management of this money. What assurances can you give us that your Institute is making careful and effective use of the appropriations we provide you?

Answer: Once funds have been appropriated by Congress, we carefully monitor their obligation throughout the fiscal year to ensure that the intent of Congress is followed. We have systems of tracking the funds which permit routine assessment of their status by programs and award mechanisms. Over sixty-five percent of NIAID's total budget supports research project grants which are subject to peer review as are the centers and National Research Service Awards. Likewise, R & D contracts undergo a similar dual review. Together, these mechanisms account for about 77 percent of our appropriated funds.

Research grant applications are subjected to a process that is based upon two sequential levels of review. The first level of review is performed by initial review groups (study sections) composed of leading university scientists selected for their competence in specific scientific areas. In considering the scientific merit of each application, the members of the initial review group (IRG) assess the scientific significance and originality of the proposed research; adequacy of the methodology; qualifications and experience of the investigator; suitability of the facilities; and the appropriateness of the budget requested.

For each application a recommendation of approval, disapproval, or deferral for additional information is made by majority vote. In addition, for each application recommended for approval, each member of the IRG individually and privately records a numerical score that reflects an evaluation of the scientific merit of the proposed research. After the meeting, the executive secretary averages the individual scores and provides a numerical rating known as a priority score.

The second review of grant applications is made by the National Advisory Allergy and Infectious Diseases Council. This group is composed of both scientific and lay representatives. Council recommendations are based on judgments concerning scientific merit as well as relevance to the Institute's program goals. We make grant awards only to those applications that are approved by our National Advisory Council.

With the budget constraints of the past few years, we have been able to fund a relatively small percentage of approved applications (29% in 1982). Thus, we are funding only those grants that have been judged by the peer review process as being the most highly meritorious of all approved applications. In regard to the Intramural Research Program, scientific merit is monitored by NIAID officials. Intramural research also receives peer review by the NIAID Board of Scientific Counselors, a distinguished group of university scientists. This process of evaluation assures the high quality of the scientific efforts of the Intramural Research Program.

Question: Aside from the peer review system, what institutional arrangements do you have that serve to deter waste, fraud or abuse in the handling of federal funds?

Answer: There are many mechanisms in place at the NIAID which serve to deter waste, fraud, or abuse. The Institute conducts continuous internal reviews, involving both extramural and intramural research scientists, for the purpose of identifying overlapping requirements and duplication of effort, certifying required levels of effort, and identifying potential conflicts of interests. NIAID Grants Management Specialists and Contracts Management Specialists are assigned the task of continually reviewing each individual grant and contract to ensure that all funded projects are free from waste, fraud or abuse. Such monitoring includes periodic site visits to contractors and grantees and comprehensive reviews of expenditures and inventories, etc. There is an extensive system of checks involving review of vouchers and financial reports and audits. Our Health Science Administrators, who receive project officer training, are responsible for monitoring and reviewing scientific progress on projects within their particular area of science expertise. Therefore, beginning with a review of the reasonableness of the budget during peer review and continuing through post-award monitoring of funds and progress, we feel we have effective control measures.

In addition, the NIAID has in place a comprehensive and centralized administrative and financial system for both pre- and post-auditing of all procurements both large and small, and also for the auditing of resource utilization (e.g., space, personnel, supplies, equipment, etc.). This system includes a series of reviews on each action taken to assure appropriateness of mechanism, procedural integrity, and adherence to all existing government and Departmental regulations. Through an extensive system of reporting and tracking, all obligations of funds are reviewed and monitored on a continuing basis at several levels to ensure their proper use. Even in the case of the most routine and recurring requirements for funding, a rejustification and reaffirmation of need is required, and must be reviewed and approved prior to obligation of funds.

DIETS AND DISEASE

Question: We continue to be interested in the possible relationship of diet to disease. We would be interested in learning whether there are cases where special diets for the sick take into account the possibility that food allergy may contribute to an illness, and eliminating the offending food provides positive results.

Answer: Allergies to several common foods (verified by means of elimination diets and oral challenge studies, skin tests and, in some instances, laboratory tests) have been shown to cause or contribute to certain specific illnesses. Special diets eliminating such incriminated allergenic foods have been documented to be of benefit in selected cases of eczema, hives, asthma, and vomiting and diarrhea.

Question: To what extent does research seek to find out which foods may be toxic and eliminate them?

Answer: Depending on the nature and timing of a symptom after food ingestion, an association between the ingestion and the reaction may be suspected. In the case of non life-threatening

reactions, research techniques can then be employed to confirm any such association. If a definite association is confirmed, researchers seek to determine the mechanism(s) of the reaction, be it toxic (poisoning after eating wild mushrooms), allergic (hives and shock after eating a peanut) or pharmacologic (water retention after eating excess salt). Once the association (with or without known mechanism(s)) is established, the usual next step to pursue is elimination of the food (for individuals in the case of peanut allergy and for whole populations in the case of wild mushroom poisoning.) Because of the NIAID mandated mission, our research thrust is directed to the study of allergic and immunologically mediated food reactions.

Question: What control studies utilizing an "eliminating" diet have been--or should be--done in this area?

Answer: Most investigations which are concerned with defining whether an ingested food substance is causing an adverse reaction in a particular patient begin by eliminating the suspected material from the diet. In this manner it can be determined whether clinical benefit results from such elimination. If benefit is noted, the offending agent may be readministered in a form unrecognizable to the patient and physician (double-blinded) in order to eliminate observer bias, and confirm the association between the food and the symptom. These studies are "controlled" in the sense that the individual, on or off the diet, serves as his own control for purposes of comparisons. In other studies where comparisons are desired between groups of people, allergic individuals may be compared with normal subjects serving as controls, both groups being subjected to a similar experiment. NIAID studies using the former study design, currently underway, are aimed at determining to what extent atopic dermatitis, behavioral changes and symptom patterns can be attributed to adverse reactions to foods.

Question: To what extent can the elimination of allergies in food help victims of, for example, hypertension or multiple sclerosis?

Answer: There are no current valid data to suggest a role for food allergy in the pathogenesis of either multiple sclerosis or hypertension. Therefore, there is no reason to believe that elimination of allergenic foods would help victims of these disorders. It should be mentioned that excess salt or licorice (glycyrrhizic acid) ingestion appears to exacerbate hypertension but likely by pharmacologic pathways rather than by allergic mechanisms.

HERPES VIRUS SURVIVAL

Question: Two researchers at the University of California at Los Angeles reported last year that their studies show that herpes genital virus can survive for long periods of time outside the body--on toilet seats, medical instruments or even gauze. Have you looked at their study?

Answer: There has been no reason to doubt the data reported by the scientists at UCLA. It has been known for some time that herpes simplex virus (HSV) can survive for brief periods outside of host cells. The survival time depends on several factors, the

most important of which is the amount of proteinaceous material present to stabilize virus viability. The virus, however, decays rapidly upon slow desiccation and is destroyed by soaps or detergents. It is unknown how much virus is required to infect a human being by mere contact of the virus with external genitalia and no studies have been proposed to date because it would require infecting nonimmune volunteers with the virus. However, based on what is known about the stability of the virus and its infectivity via dermal contact in animals, little credence is given to the possibility of transmission via toilet seats. Transmission via shared bath towels is more plausible if the towel is not laundered after use by a person with active lesions.

Question: And how significant is it?

Answer: Recovery of HSV from surfaces is not quantitative and is subject to considerable technical problems. Thus, results of such tests are highly variable and difficult to interpret regarding transmissibility.

Question: What research is being done to substantiate these findings?

Answer: No research projects currently supported by NIAID are investigating the survival time of HSV on inanimate surfaces. There are studies being supported, however, to detect and quantitate the virus in individuals who may shed virus without clinically detectable lesions and in individuals with overt lesions. The experimental data indicate that infectious virus is extremely difficult to detect unless from open, active lesions. These are important epidemiological questions and for that very reason we have had one center studying for 5-6 years the epidemiology of herpes infections so that investigators could examine all of the various issues that might be involved in its spread. Just this past year we have funded a second new major epidemiological study on the spread of herpes in the population and on the natural history of this infection. It is just these sorts of questions that you ask that we hope to answer from these epidemiological studies. In addition, this research will lay the groundwork so that we will be better prepared to select the right populations to receive the herpes vaccine when it is available.

Question: And what are the implications for public health?

Answer: There are no data available yet to estimate the threshold of infectious virus required to transmit an infection to another individual. The question is very important, however, and studies will continue in pregnant women near term with histories of recurrent genital infections and in sexual partners of patients with recurrent disease to further refine our estimates of the risks of transmission from mother to neonate and from adult to adult. Such studies are being supported by NIAID at two large clinical centers in Seattle and Atlanta. Interruption of transmission is the ultimate answer to control of infection.

HEPATITIS B VACCINE

Question: We were all pleased that the Hepatitis B vaccine finally was licensed and is both available and found to be effective. However, it is somewhat disturbing to learn of its high

cost and the technical difficulty in producing it. What are you doing to develop a less expensive form of the Hepatitis B vaccine?

Answer: The development of an effective hepatitis B vaccine was a long-awaited product for our disease-prevention armamentarium. Because the hepatitis B virus has not been grown in the laboratory, the vaccine antigen must be recovered from the plasma of humans chronically infected with the virus. Subsequent purification, inactivation, and safety tests are quite extensive and the resultant vaccine is very costly.

Non-clinical sources for the surface antigen of hepatitis B virus (HBsAg) are being investigated in university and NIAID laboratories and in private industry. The complete genome of the hepatitis B virus has been sequenced and specific genetic information coding for the vaccine antigen has been incorporated into bacteria, yeasts and viruses. Hepatitis B antigen has been successfully produced by use of recombinant DNA technology, but thus far yields are too low for use in vaccine production. Additional developmental work is required.

Small fragments of polypeptides that make up the vaccine antigen have been chemically synthesized and are being evaluated in chimpanzees as potential immunogens. This work is being performed by NIAID-supported investigators. Although the potential appears good for the eventual use of polypeptide antigens, considerable developmental effort is required before this potential is realized. A very new and novel approach concerns the creation of a hybrid vaccine from a combination of the genes of the hepatitis virus and vaccinia virus (smallpox vaccine) which upon administration would render the recipient immune to both infections.

Question: And when may we expect it to be licensed and made available to the general public?

Answer: Investigators believe that 2-4 years may elapse before a second generation hepatitis B vaccine will be licensed and made available to the general public.

National Institute of General Medical Sciences

STATEMENT OF DR. RUTH L. KIRSCHSTEIN, DIRECTOR

ACCOMPANIED BY:

DR. JAMES B. WYNGAARDEN, DIRECTOR, NIH
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BUDGET REQUEST

Senator Weicker. The next witness is also very familiar to the subcommittee. We are glad to welcome back Dr. Ruth Kirschstein, Director of the National Institute of General Medical Sciences.

The Institute is deeply involved in vital research on the cell and gene and provides for the training of many of our future health researchers.

The revised budget request for the Institute is $383 million or about $8 million more than the January request and some $13.5 million more than the fiscal 1983 funding level.

Dr. Kirschstein, please go ahead with your opening statement.

Dr. Kirschstein. Mr. Chairman, I would like to introduce Mr. William Fitzsimmons, the Executive Officer of the Institute.

This year marks the 20th anniversary of the establishment of this Institute which was authorized by Congress in 1962 to conduct and support research and research training in the basic medical sciences.

NIGMS has a unique place within the NIH because it is the role of NIGMS to support fundamental untargeted investigations that have generated, and will continue to generate, the knowledge and concepts which have led to the biological revolution that you have heard so much about today.

These investigations generate concepts which are not necessarily immediately relevant to any particular disease, but ultimately form the foundation for subsequent research strategies developed at more disease-oriented levels. The clearest example is that of the studies leading to the development of recombinant DNA technology which has, more rapidly than any of us ever imagined, led to the production of important products useful for various diseases, products, such as human growth hormone and interferon.

About 70 percent of the research supported by NIGMS involves the study of cell structure and function, as well as of genetics, studies that seek insights into the molecular mechanisms which maintain human health, and which, if they go awry, can cause disease.

Over the past few years, we have made many great strides in our understanding of the nature of the genetic material of living creatures at all levels of complexity. And now, we face the exciting prospect of rapid progress in research on the genetic material of man. Fundamental to this is the creation of a map of the genes along the chromosome.

New methodologies are now available to allow scientists to map and understand the tremendously complex human genome. And our understanding of how each piece of the genetic material works is increasing rapidly. We are beginning to see how the function of genes is controlled in specific cases and how this control might be modified. For example, we have tentative ideas as to why chromosome rearrangements can lead to a number of genetic defects, as well as perhaps to cancer, and why some genes that work perfectly well in the fetus are indeed turned off in the adult.

Fundamental understanding of the basic mechanisms underlying all of these phenomena is the goal of the research supported by NIGMS. I believe the payoff in terms of human health and disease is already beginning to be apparent.

NIGMS supports two resources that are very critical to this research area. One is the human mutant cell repository which provides the cellular materials with which gene mapping can be done, particularly cell cultures from persons with genetic defects.

For example, we have in this collection many cell lines from the Huntington's disease victims being studied in Venezuela as Dr. Goldstein described.

The other resource is a new effort called GenBank which is a collection of all nucleic acid sequence data that have been published. We have had support in establishing this resource from not only the other Institutes at NIH, but from many other agencies of the Government as well.

Finally, it should be noted that, in establishing the NIGMS 20 years ago, Congress included in its mission support of research training to serve the future research programs of NIH as a whole. The high standards established by the training grant and fellowship programs of the NIGMS will assure the Nation that biomedical research in future years will be of the same high quality that has prevailed in the past and that the graduates of such training programs will have the versatility to meet the scientific problems of the future.

The NIGMS remains committed to training research scientists and to the support of untargeted biomedical research which can be expected to lead to the understanding, prevention, and treatment of currently poorly understood human disorders.

But it should be emphasized that we still have so much to learn, and that to sustain this momentum, we must continue to progress.

I should be pleased to answer any questions.

IMPACT OF FUNDING LEVELS ON RESEARCH CAREER CHOICES

Senator WEICKER. Let me ask you the question I asked Dr. Goldstein, I think, before, but it seems to me particularly applicable to your Institute—this roller coaster funding operation.

In your discussions with the research community, those that are contemplating research as a career, what is the effect of that? I don't refer now just to this administration. Obviously, it goes through administrations. And where do we sit as research is perceived now by both student and those engaged in it?

Dr. KIRSCHSTEIN. Mr. Chairman, this is a very serious problem. As young people begin to plan their careers, they have to see a pattern in the future which is stable enough to allow them to plan along the way. Research, the dedication to research, requires a long-term commitment on the part of the student and the faculty member.

After graduating from college an individual who embarks on a career of learning to be a researcher either by going to medical school because he wants to do specific medical research, or by attending graduate school because he perhaps wants to do more fundamental research, must be able to chart a course that will take years to accomplish.

In the plans that he makes for his future, he uses role models almost continuously. These are the individuals around him, his teachers and his preceptors. Indeed, the career choices that a student makes are often dependent upon what the morale and the philosophies of his mentors are. As he plans his career, this roller coaster phenomenon, to which you refer, has a profound influence.

IMPACT OF REVISED BUDGET

Senator WEICKER. How is your Institute impacted by the competing grants adjustment both as it relates to the numbers and then as it relates to those other activities which are being cut to achieve the savings?

Dr. KIRSCHSTEIN. Mr. Chairman, the original January budget submission of the President provided for the support of 552 new and competing research grants by NIGMS. The current plan provides for 721 new and competing research grants, an increase of 169.

Our Institute, being the basic science Institute, supports a very large share of the investigator-initiated research funded by NIH. Our portfolio of other activities, other than research training, is much smaller than those of the other NIH components.

However, we are the preeminent Institute in research training. We support about one-third of all the trainees funded by NIH and about two-thirds of all predoctoral trainees.

In addition, we have a unique program of research training, namely the medical scientists training program which trains physician scientists, students who are studying for the combined M.D., Ph. D. degree. These are the medical scientists of the future. Research training support was constrained in the January budget, but has been somewhat more curtailed under the current plan due to the elimination of the planned 5-percent increase in the stipends provided to trainees.

RESEARCH CENTERS

Senator WEICKER. With regard to your research centers, two of the following would not be funded: University of Iowa; State University of New York; University of California, San Francisco; Trauma and Burn Centers, University of Texas and Cornell University Medical Center; Anesthesiology Research Center, Harvard; and Genetics Research Center, University of Pennsylvania.

Two of these will not be funded; is that correct?

Dr. KIRSCHSTEIN. Mr. Chairman, all of these research center grant applications are up for competing renewal in fiscal 1984. The peer review process has not taken place as yet, so that it is not possible to determine exactly what will happen to them. However, under the current plan, it would not be possible to fund two of these.

ROLE OF NIGMS

Senator WEICKER. I am not advocating this, but just so I get clear in my mind what it is your Institute does, let me put this type of question to you: Why shouldn't your Institute be split up and be merged into the existing Institutes? Does it accomplish something unique, in other words, that is not covered by any of the other Institutes?

Dr. KIRSCHSTEIN. Yes; I think it does.

Senator WEICKER. Or are you more or less a short fielder for safety insofar as backing up that area?

Dr. KIRSCHSTEIN. No; I don't think so. It is our unique mission to support the basic fundamental research activities which I discussed earlier. These studies, as they develop applicability to specific diseases fan out and are picked up by the other Institutes. When studies in cell biology, basic genetics, biochemistry, and biophysics are undertaken, the researcher does not know what particular categorical area—heart disease, cancer, neurological diseases, dentistry—may be the target of the discoveries he will make.

Indeed, some of the most fundamental discoveries as in the case of the recombinant DNA technology developed by NIGMS grantees have had an impact on all disease categories. Therefore, there has to be an undergirding Institute, if you will, which supplies basic information which, as it develops, may indeed impact, for example, on cancer research. Then those activities are transferred to support by the Cancer Institute or, if the emphasis becomes heart disease, at another time to the Heart Institute.

But it is not possible to determine in advance what knowledge from basic studies will lead to a particular facet of a particular disease.

FUNDING PRIORITIES

Senator WEICKER. What are the priorities going on in your Institute right now?

Dr. KIRSCHSTEIN. The excitement of the last 10 to 12 years, the biologic revolution that everyone has mentioned, has come out of many of

the studies in genetics and cell biology that this Institute has supported. And the priority of our Institute is to continue to support the gathering of basic fundamental knowledge in cellular and molecular biology and in genetics.

PREPARED STATEMENT AND SUBMITTED QUESTIONS

Senator WEICKER. All right. Thank you very much. I appreciate your testimony.

There are further questions that I would appreciate your responding to for the record.

Dr. KIRSCHSTEIN. Thank you, sir.

[The information follows:]

Statement of Dr. Ruth L. Kirschstein

Once again, I am honored to present to you the programs of the National Institute of General Medical Sciences. This year marks the 20th anniversary of the establishment of this Institute, authorized by the Congress in 1962, "to conduct and support research and research training in the general or basic medical sciences. . . ." The wisdom of the Congress that long ago in foreseeing the importance of basic biomedical discoveries and the enormous burst of knowledge which has taken place in the fields of molecular biology, genetics, biochemistry, biophysics and molecular pharmacology cannot be overstated.

This Institute has, indeed, provided support to a number of extremely important areas of research over the past 20 years. Such studies have yielded new perspectives and knowledge as well as new instruments which have allowed the development of improved treatments, diagnostic tools and methods of prevention based on a better understanding of the underlying mechanisms of disease. Among the key contributions made by NIGMS grantees are the following:

- o Understanding of the role of nucleic acids in the process of cell division, the synthesis of cell components and the transmission of inherited characteristics;
- o Development of new methods for mapping genes on chromosomes and the elucidation of chromosomal structure;
- o Development of recombinant DNA technology; and
- o Elucidation of the structure and function of biologically important macromolecules and, particularly, of the proteins in cellular membranes.

These developments have made this a particularly exciting period during which great leaps forward are being made in man's understanding of his own biology.

Many of the achievements of the grantees of the Institute are summarized in the booklet, "Decade of Achievements," which I should like to submit for the record. I would like now to highlight some of the most recent significant advances.

Genetics Program

Members of the Committee are well aware of the remarkable explosion of knowledge which has led to the development and application of recombinant DNA technology. I would like to tell you now about yet another highly important advance in methodology developed by NIGMS grantees. This is *in situ* hybridization, an elegant technique for actually mapping the locations of specific genes on chromosomes. It works as follows: Genes from higher organisms such as the fruitfly, Drosophila, are cloned in bacteria, reisolated and labeled with specially marked DNA precursors, so that the copies of the cloned gene can be easily detected. The cloned genes are then used as "probes" that bind, or hybridize, to that region of the fruitfly chromosome which contains a DNA sequence similar to that of the probe. The location of the probe *on* the chromosome is then

detected under a microscope by one of several methods, depending upon how the cloned gene was marked. The original method, devised in 1969 by Drs. Joseph Gall and Mary Lou Pardue at Yale University, used radioactive DNA precursors to mark the gene, and the radioactive gene probe was detected by its ability to expose X-ray film.

Recently, Dr. David Ward, also of Yale University, has developed an elegant modification of *in situ* hybridization in which the position of the cloned gene can be visualized by fluorescence microscopy. Dr. Ward's procedure is rapid and inexpensive, and circumvents the need for using radioactive chemicals. Continued improvements have made the technique so sensitive that he now can detect the presence of even a single copy of a gene on a mammalian chromosome. The ability to map genes precisely is important for understanding the regulation of gene activity and the subtle changes in chromosomes during development and evolution. *In situ* hybridization will also improve prospects for genetic screening and prenatal diagnosis of genetic defects.

Cellular and Molecular Basis of Disease Program

Grantees supported by the Cellular and Molecular Basis of Disease Program are making efforts to better understand the structure and functions of the fundamental unit of the body, the cell. We know that the cell is surrounded by a membrane, in which there are channels or pores which regulate the transport of vital chemicals in and out of the cell. In order to learn more about this mechanism of transport, NIGMS grantees have constructed synthetic channels, one of which is made by a chemical, gramicidin A, which is inserted into the membrane. This relatively simple substance selectively permits transport of ions and electrolytes across the membrane. It has been shown that this selectivity resembles that of many naturally occurring membrane channels. An NIGMS grantee, Dr. Olaf Anderson of Cornell University, has been investigating the biophysical aspects of transport through the gramicidin A channel, and has concluded that positively charged ions (called cations), like hydrogen or calcium are transported through the channel by a "single file" process. This important new finding means that cations and water molecules cannot pass each other in the channel, and that the rate of transport of the ion is limited by the number of water molecules which must be moved with it.

There is now considerable evidence that the natural membrane channels in nerve and muscle cells also permit transport only in single file, and it is possible that dysfunctions of these cells may be related to the disruption of this orderly flow. Thus, synthetic channels are extremely valuable model systems, the study of which may elucidate the underlying mechanisms of diseases which we do not yet understand.

Pharmacological Sciences

An important area of today's research in the pharmacological sciences involves the study of prostaglandins, chemicals which mediate a wide range of important physiologic and pathologic functions. Indeed, the 1982 Nobel Prize in Physiology or Medicine was awarded for discoveries concerning prostaglandins. Many NIGMS grantees are studying these substances and some are having great success. Among them are Dr. John Oates of Vanderbilt University in

Nashville, Tennessee, and Dr. Vincent Ziboh at the University of California at Davis. Dr. Ziboh has been investigating the role of prostaglandins in the production of the blood-forming cells. Primitive "stem cells" from the bone marrow normally differentiate into either granulocytes, white blood cells which form pus and fight bacterial infections, or into macrophages, the scavenger cells. When these "stem" cells are stimulated to multiply and differentiate, a chemical called arachidonic acid is released. Arachidonic acid is then transformed by a series of intermediate steps into either prostaglandins or another group of related substances known as leukotrienes.

Dr. Ziboh believes that it is this intermediary series of products which is responsible for the stimulation of growth and differentiation of granulocytes and macrophages. He found that when he added a selective inhibitor of leukotriene production, differentiation of stem cells was suppressed, whereas an inhibitor of prostaglandin production had no such inhibitory effect. Thus, these ubiquitous chemicals seem to be important in mediating the maturation of blood cells essential to combating infection. Much further study is needed to fully understand the biological importance of arachidonic acid and its products, but such research may well provide the basis for the future development of important pharmacologic agents.

A major reason for the marked advances now occurring in basic biomedical science has been significant improvements in research instrumentation and techniques, many of which have been products of NIGMS support. For example, protein purification methods have been continually improved, and sophisticated electrophoresis separation techniques in both one and two dimensions have been developed. One result is that a surprising variety of previously unknown cellular proteins has been discovered in recent years. In addition, X-ray crystallography and electron diffraction techniques are now being used to study the structure of nucleic acids and chromosomes, as well as subcellular organelles, called ribosomes, which translate genetic information into protein production.

One of the most exciting recent developments has been in nuclear magnetic resonance (NMR) spectroscopy, which is being used to study many of the constituent chemicals of the cell including proteins and nucleic acids. Rapid development of this research tool is now making it possible to analyze NMR signals from intact tissues and organs, thus permitting studies of living tissues. This non-invasive technique is already beginning to provide invaluable insights into the complex regulatory processes of whole organs and tissues. It is likely that we will soon be able to assess the biochemical consequences of severe dysfunctions, such as stroke, on the central nervous system.

Burn and Trauma Research

The artificial skin developed by Drs. John Burke and I. V. Yannas, of the Massachusetts General Hospital and the Massachusetts Institute of Technology, about which I have reported to this committee in the past, is undergoing further development. Drs. Burke and Yannas are now using the burned patient's own cells from the deepest skin level (basal cells) to seed a two-layered artificial membrane with the beneficial result that proliferation of these normal skin cells gradually and more completely fills in the wound.

This continued progress toward the development of a total skin substitute for use in the treatment of severely burned patients is most gratifying.

Research Training

In establishing the National Institute of General Medical Sciences 20 years ago, the Congress included, in its mission, the support of research training to serve the future research programs of NIH as a whole. The high standards established by the training grants and by fellowship support provided by NIGMS have assured the Nation that biomedical research in future years will be of the same high quality that has prevailed in the past and that the graduates of such training programs will have the versatility to meet new scientific problems. In the past 20 years, the research training programs of the Institute have evolved and, at present, we give high priority to the training of predoctoral students in basic multidisciplinary areas as well as to the Medical Scientist Training Program designed to provide a combined M.D.-Ph.D. degree, and to the Minority Access to Research Careers Program, designed to increase the number of minority scientists entering into fundamental biomedical research.

As the National Institute of General Medical Sciences begins its next 20 years, it is clear that scientists are only beginning to understand the basic underlying mechanisms of many diseases, despite the enormous progress that has already been made. Most of the advances of the past 20 years would have been impossible to predict. Many of our concepts about cells and genes have undergone revolutionary changes as a result of unexpected discoveries made in this period of time.

Yet, despite this rapid progress, we still know so little. As we have seen in the past, studies of fundamental cellular and biochemical mechanisms frequently lead to findings of great importance to the understanding, prevention, and treatment of human disease. The Institute remains committed to train research scientists and to support untargeted biomedical research which can be expected to build on the bases outlined above to produce even greater achievements in the future.

Mr. Chairman, to sustain this momentum, the budget request for the National Institute of General Medical Sciences for Fiscal Year 1984 is $383,139,000. I shall be pleased to answer any questions and to supply any additional information you may request.

BIOGRAPHY OF DR. RUTH L. KIRSCHSTEIN

POSITION:	Director, National Institute of General Medical Sciences
BIRTHPLACE and DATE:	Brooklyn, New York October 12, 1926
EDUCATION:	A.B., magna cum laude, Long Island University, 1947 M.D., Tulane University School of Medicine, 1951

EXPERIENCE:

Director, National Institute of General Medical Sciences, September 1974-present
Deputy Associate Commissioner for Science, FDA, 1973-1974
Acting Deputy Director, Bureau of Biologics, FDA, 1972-1973
Assistant Director, Division of Biologics Standards, NIH, 1971-1972
Chief, Laboratory of Pathology, DBS, NIH, 1965-1972
Acting Chief, Laboratory of Pathology, DBS, NIH, 1964-1965
Assistant Chief, Laboratory of Viral Immunology and Chief, Section of Pathology, DBS, NIH, 1962-1964
Chief, Section of Pathology, Laboratory of Viral Immunology, DBS, NIH, 1960-1962
Medical Officer, Pathologist, Laboratory of Viral Products, DBS, NIH, 1957-1960
Medical Officer, Resident in Pathology, Clinical Pathology, Clinical Center, NIH, 1956-1957
Trainee of National Heart Institute and Instructor in Pathology, Tulane University School of Medicine, 1954-1955
Resident, Pathology, Providence Hospital, Detroit, Mich., 1952-1954
Assistant Resident, Pathology, Veterans Administration Hospital, Chamblee, Ga., 1952
Internship, Medicine and Surgery, Kings County Hospital, Brooklyn, N.Y., 1951-1952

CERTIFICATION:

Medical Specialty Board Certification, Pathology (anatomic and clinical pathology), 1957

ASSOCIATION MEMBERSHIPS:

American Association of Immunologists
American Association of Pathologists
American Society of Microbiology

SPECIAL AWARDS or CITATIONS:

Institute of Medicine, National Academy of Sciences, 1982
Presidential Meritorious Executive Rank Award, 1980
PHS Superior Service Award, 1978
DHEW Superior Service Award, 1971

COMMITTEE MEMBERSHIPS:

Invited member of World Health Organization Expert Group on International Requirements for Biological Substances, Geneva, Switzerland, 1965 and 1971
Invited consultant to World Health Organization concerning problems related to the use of Poliovirus Vaccine, Live, Oral. Geneva, Switzerland, 1967
Member, Primate Research Centers Advisory Committee, Division of Research Resources, NIH, 1971-1975
Member, National Commission on Diabetes, 1975
Member, National Commission on Arthritis and Related Musculoskeletal Diseases, 1975
Member, Ad Hoc Committee on Reserpine and Breast Cancer, 1974-1977
Chairperson, NIH Grants Peer Review Study Team, 1975-1976
Member, Scholars-in-Residence Advisory Committee, 1977-1982

Questions Submitted by the Subcommittee

NEW BUDGET FOR '84

Question: We would like to get your perspective on how the revised NIH budget for FY 1984 affects your Institute.

How many additional new and competing grants will you get above the January budget--and what further research will you be able to do as a result?

Answer: The President's revised 1984 budget for the National Institute of General Medical Sciences (NIGMS) provides for 721 new and competing research project grants. This represents an increase of 169 grants over the original total of 552 awards provided for in the President's January budget. These additional grants have been allocated by program as follows:

Program	Additional Research Project Grants
Cellular and Molecular Basis of Disease....	+62
Genetics.....	+66
Pharmacological Sciences.....	+25
Physiology and Biomedical Engineering.....	+16
Total.....	+169

As indicated, research studies in the fields of basic cell biology and genetics would benefit most. The revised President's budget would specifically allow the NIGMS to support additional research projects concerned with further development of gene mapping and recombinant DNA technology; study of transposable genetic elements; and study of the role of a wide variety of proteins and cellular organelles in both health and disease. Additional studies concerned with the mechanisms of drug action and the development of improved research laboratory instruments would also be supported.

Question: It is our understanding that the January and April budgets both assume cuts in the average award for new and competing grants below what the full average cost would be. For new grants this appears to be a difference of some $17,800 ($142,400 full cost vs. $124,600 in revised budget). How will this affect your Institute --and to what extent will it start changing the scope and quality of the projects that are reviewed by your study sections?

Answer: The January and April budgets do assume cuts in the average award costs for new and competing research grants from projected study section recommendations for FY 1984. However, the amounts budgeted for new and competing research project grants in the April budget still include an increase in the average cost of these awards over the FY 1983 budget. Even when this increase is offset by the proposed reduction in indirect costs from FY 1983 to FY 1984, the FY 1984 average cost still increases by about 5% over the FY 1983 average cost.

For NIGMS, the reductions from the study sections' recommended "full cost" levels for new and competing grants in FY 1984 will average about 14%--a reduction from a mean of $134,800 to $115,600. Reducing the amount of funds allocated to a research project grant in this way may have the effect of slowing the pace at which the

investigator involved can proceed with his or her research. "Cutting corners" also may have the effect of compromising the quality and scope of projects already reviewed and approved by the NIH study sections, which are responsible for assessing the scientific merit of research applications, and also adjusting the associated costs to what they feel are appropriate levels. Whether and to what extent these proposed budget reductions actually will impact negatively cannot, however, firmly be determined at this time.

Question: Under your budget revision, the average NIH noncompeting grant award is projected to decrease by about $12,400 below what the full average cost would be ($143,100 full cost vs. $130,700 in budget revision). How will this affect your Institute--and to what extent will it change the scope and quality of the projects that are reviewed by your study sections?

Answer: For NIGMS, the average reduction for noncompeting awards will be approximately $9,800, from $126,400 full cost to $116,600 in the revised budget. Even with this reduction, however, the FY 1984 budget still shows an increase of about 3% over the FY 1983 average cost for noncompeting awards.

The effects of reducing the average size of noncompeting awards below full recommended costs levels are likely to be similar to the effects of reducing new and competing awards, although the reductions being proposed are somewhat smaller for the former. Projects in the noncompeting category (which are also referred to as continuation grants) are not reviewed by study sections until the end of a 3 to 5 year funding period, but any obvious changes in scope or quality in these grants would, of course, be noted and assessed by Institute staff on an ongoing basis. At the moment, there is no way to predict the effects, if any, of the proposed reductions with any certainty.

Question: The Administration proposes to make cuts from the January budget in grants to specialized and comprehensive research centers. How does this affect your program--and what will it do to research at those centers?

Answer: The NIGMS allocation for the support of research center grants has been reduced from $10.6 million in the January budget to approximately $8.4 million in the revised budget. This reduction has required both the elimination of proposed support for two (2) research center grants (one in trauma and burn research and one in pharmacology-toxicology research) and a reduction of 15 percent in the average size of the 17 research center grants remaining in the budget. The primary effect of these cuts will be a reduction in collaborative efforts between clinical investigators and laboratory scientists in the areas of trauma and burn and pharmacological research and a slowing down of the pace of research activities at the remaining centers.

Two (2) of the following five (5) NIGMS research centers will not be funded in 1984 as a result of the changes made to the President's January budget for the NIGMS.

Research Centers

Institution/Location	Estimated FY 83 Support
Pharmacology-Toxicology	
University of Iowa, Iowa City	$883,000
SUNY at Buffalo	376,000
University of California, San Francisco	320,000
Trauma and Burn	
University of Texas, Dallas	$254,000
Cornell Medical College, New York	339,000

Question: To what extent will any clinical trials be affected by the proposed cuts in research and development contracts and cooperative clinical research?

Answer: As the basic science institute, the NIGMS does not support any clinical trials per se. Thus, the proposed NIH-wide cuts in research and development contracts and cooperative clinical trials will not directly affect NIGMS sponsored activities or programs in this area. The NIGMS focuses its funding support on basic untargeted research studies, including studies of the mechanisms of inheritance and cellular structures and functions, which lead, ultimately, to clinical applications. Discoveries emanating from such studies are frequently critical to later development by grantees of the other institutes of strategies for clinical intervention.

Question: The new budget proposes to eliminate the 5% stipend increase for predoctoral and postdoctoral training, to make further reductions from the January budget in the number of trainees, and to decrease the number of research career awards to promising scientists. What effect will these steps have on your Institute's training program--and what effect will it have on young people contemplating careers in biomedical research?

Answer: The changes proposed between the January and April budgets do not include reducing the number of research trainees supported by the NIGMS. While the other measures mentioned may make recruitment of trainees more difficult in the short run, we feel that the most important factor in attracting young people into research careers is the long range prospect that there will be reasonably stable grant support available for biomedical research.

Question: To what extent will the proposals to reduce funding for general clinical research centers and biomedical research support grants affect biomedical research in general and your Institute's work in particular?

Answer: The General Clinical Research Center and Biomedical Research Support grants have provided support for research-related functions at NIGMS grantee institutions in a flexible and efficient manner. In 1982, 48 NIGMS supported research grants, costing approximately $10 million, relied upon the trained staff, research beds, equipment, and clinical environment provided by the General Clinical Research Center Program to carry out projects in such areas as trauma and burn and anesthesiology research. In the same year, 485 NIGMS supported research grants, costing approximately $50 million, were awarded to institutions which also relied upon funding provided by the Biomedical Research Support Grant award mechanism to supplement or complement their basic biomedical research efforts. NIGMS grantees will have to provide for the loss of funds in these two

areas from their own research project grant budgets or seek assistance from their institution or other sources.

"EXCITING" DISCOVERIES

Question: Your justifications use such words as "exciting," "startling," "dramatic" and other equally compelling adjectives to describe some of the research work you support.

We certainly hope that the use of this emphatic language is not simply "hype" for our benefit, but reflects results that soon will be helpful to the work of the other institutes and to the general public. What can you tell us?

Answer: The NIGMS is not alone in exhibiting a high degree of enthusiasm for research developments in the fields it supports, most particularly with regard to genetics and cellular and molecular biology, to which over 70% of the Institute's budget is allocated. For example, the Office of Science and Technology Policy, in its "Annual Science and Technology Report to the Congress: 1981" (dated April 21, 1982) stated the following:

> "During the past few years, discoveries about the hereditary material inside the cell have opened new worlds in biology. A quantum leap has occurred in our understanding of the way genetic information is encoded and transmitted. Researchers are tantalizingly close to identifying the fundamental defects in specific genetic diseases and to answering such key questions as how cells differentiate to serve specialized purposes; why some cells become malignant, and why cells eventually age and die. Today, all the essential elements for momentous research advances in genetics are at hand..."

This same report notes that, "much of the fundamental work in genetics has been funded by the National Institute of General Medical Sciences in the National Institutes of Health..."

Clearly, there are many "exciting" and "dramatic" advances occurring in the area of genetics research; the same is also true in cell biology. Discoveries concerned with the structure, synthesis, and function of proteins (including enzymes and hormones) and cellular organelles are leading to a much clearer understanding of disease. The discovery, by an NIGMS grantee, of a possible link between sodium and lithium transport in red blood cells and high blood pressure, for example, has led to a number of important studies over the past year which are exploring a possible test to determine at an early stage an individual's predisposition to essential hypertension (high blood pressure), which now affects 9% of the U.S. population.

Question: Can you provide us with any examples of "exciting" discoveries or developments coming out of your Institute in the last year that provide hope for "pay offs" to the public in the not-too-distant future?

Answer: The basic research supported by the NIGMS is long-term in nature, with only occasional "quick applications" of new discoveries. Indeed, it is the nature of science in general that major breakthroughs are normally the product of the slow accumulation of knowledge by scientists working independently over a period of years.

Results helpful to the work of the other NIH institutes and to the general public are, however, constantly being produced by NIGMS grantees.

Exciting discoveries by NIGMS grantees over the past year, which hold out significant hope for "pay-offs" to the public within a reasonably short period of time, have been made in the following areas:

1. Pencillin Resistance: Some pathogenic bacteria are not destroyed by pencillin because they possess an enzyme which can inactivate this otherwise powerful drug. Dr. Jeremy Knowles, an NIGMS grantee at Harvard University and Dr. James Knox, a grantee at the University of Connecticut, have determined the biochemical proc-

esses by which this enzyme functions; and this new information can be expected to contribute significantly to the development of new compounds to combat pencillin-resistant infections.

2. Treatment of Malaria: In the past 10 years, there has been a major resurgence of malaria world-wide, with a 2.3-fold increase in prevalence reported by the New England Journal of Medicine. There has also been an increase in the number of cases imported into the United States by Southeast Asian refugees, returning Vietnam War veterans, and U. S. citizens who have travelled to Asia. A recent discovery in the laboratory of Dr. David Dressler, another NIGMS grantee at Harvard, now shows great promise for a new, effective method for treating this troublesome disease. Dr. Dressler's research began simply as the study of a basic cell process, DNA replication, and the search for an ideal model system. The fortuitous discovery of a potential treatment for malaria is an important event arising from basic science.

3. Treatment of Viral Infections: Viral infections are among the most difficult diseases to treat, in part because viruses are very successful in adapting to or evading both the host's natural defenses and man-made treatments. Dr. Gisela Mosig, an NIGMS grantee at Vanderbilt University, has been studying the initiation of DNA replication in a specific virus and has recently come up with findings which shed new light on an important topic--how viruses reproduce during an infection. Dr. Mosig has also elucidated the basis for some of the resistance of viruses to host defenses; specifically, that the "recombination initiation pathway" makes them virtually independent of their hosts. This discovery, by itself, should be of major importance in finding ways to combat viral infections.

4. Treatment of Neurological Disorders: As noted in the narrative justification for the Pharmacological Sciences Program, Dr. Nicholas Boder, an NIGMS grantee located at the University of Florida, has developed a new and apparently successful technique for delivering drugs selectively to the brain, thus penetrating the "blood-brain barrier"--up until now a major impediment to the treatment of a variety of neurological disorders. The availability of this technique does not mean that it is going to be immediately possible to cure previously untreatable diseases, but it does mean that it probably will be possible to deliver more effective concentrations of therapeutic drugs to the brain.

5. Diagnosis of Genetic Diseases: The NIGMS supports an important group of research projects focused on "gene mapping," the proc-

ess of locating the specific site of an individual gene on one of the 24 pairs of human chromosomes. Although still in its infancy, this area of study is already proving to be very fruitful, both in terms of providing a research tool for university scientists, and in terms of providing a potential aid in identifying incipient genetic disease. Indeed, scientists supported by the NIGMS are moving close to the point where it will be possible to identify clear linkages between a known gene or DNA enzyme cutting site and the presence of a disease, making it possible to determine whether a currently unaffected family member is a carrier of a disease or is directly at risk. Such a tool would be very valuable in diagnosing disorders such as cystic fibrosis or Huntington's disease. Within the past year, NIGMS grantees at the California Institute of Technology (N. Davison) and Yale University (D. C. Ward) have developed novel modifications to the "in situ hybridization technique," a widely used procedure for gene mapping, which should improve dramatically the prospects for the diagnosis of genetic defects.

6. Treatment and Prevention of Heart Attacks: Dr. Roberto Levi, an NIGMS grantee at Cornell University, has discovered the existence of an important relationship between cardiac arrhythmias, or irregular heart beats (including usually fatal ventricular fibrillations), and two chemicals which occur naturally in the body: leukotrienes and histamines. This has opened up the possibility of treating and/or preventing acute and potentially fatal heart attacks through the use of a combination of certain antihistamines and leukeotriene synthesis inhibitors.

PHARMACOLOGY

Question: Your pharmacological work, even in your revised budget, gets the biggest increase--$4.9 million--of any of the research areas in your Institute.

We recognize the critical work being performed here, but your key research areas continue to be the cell and the gene. How do you explain this?

Answer: In FY 1984, the relative proportions of the total NIGMS budget devoted to each of the Institute's scientific programs will be relatively unchanged from recent years, with research in basic cellular and molecular biology and genetics receiving about 70% of Institute funds. This reflects the Institute's decision to continue to focus its support in those areas where the very best and most promising research ideas are developing. In the past two years, this philosophy and funding strategy have also meant that increased numbers of grant applications in the pharmacological sciences have been funded because of their scientific merit and promise. These grants carry commitments into FY 1984, which account for the large increase in the budget for this program. It should also be noted that much of the research funded by the Pharmacological Sciences Program is oriented to studying the molecular, cellular, and genetic components of, or contributors to drug activity, so that these studies may be viewed as part of the Institute's general emphasis on basic studies in these areas.

Question: Your justification says you're pleased at the number of high quality research applications being received in pharmacology, but the number of new and competing grants in the January budget was projected to drop by 49, and the revised budget won't change that

very much. Isn't there a contradiction in your statement?

Answer: There is no contradiction, in that our statement refers to the increase in high quality applications received since 1981, many of which were funded over the past two years and are reflected in the 1984 budget as noncompeting continuations. Previously, a lack of high quality applications had prompted the Institute to plan for budgetary reductions in the Pharmacological Sciences Program for 1983 and 1984.

INTRAMURAL RESEARCH

Question: You have a unique intramural research program which seems to be more a training ground for future pharmacologists than it is the traditional in-house research program we find in other institutes.

Why don't you simply call it another training program and let it go at that?

Answer: The Pharmacology Research Associate Training (PRAT) Program differs from other NIGMS sponsored training activities in that: (1) The individuals selected for this program are given status as NIGMS employees under authority of Section 207(g) of the Public Health Service Act; and (2) The trainees work in NIH laboratories in Bethesda, while receiving on-the-job training and instruction from leading scientists in their fields within the NIH intramural research community, rather than working in other institutional settings. Over the years, this program has been quite successful, both in developing outstanding young scientists and in encouraging inter-Institute collaborations within the NIH, which would have been difficult to achieve without this Program. Of the 156 individuals trained to perform pharmacology research in the PRAT Program, approximately 140 currently have responsible positions in academic institutions, in industry and in Federal laboratories doing such research.

Question: Why limit the program to drugs--why don't you select people to do research on cells and genes as a complement to your extramural program?

Answer: The answer is historical. The NIGMS grew out of a strictly extramural NIH organizational component, the Division of General Medical Sciences, being designated a research institute by the Congress in 1962, responsible for the support of "research and research training in the general or basic medical sciences." In 1965, Dr. James Shannon, then Director of NIH and himself an eminent pharmacologist, felt that there was a need to increase the number of well-trained investigators in the basic pharmacological sciences. Knowing that this area of research was already fairly strong within NIH's intramural programs, he established the PRAT Program as an activity within the otherwise solely extramural NIGMS, with the specific purpose of providing a focus for pharmacological research training which could cut across the disciplinary lines of the various categorical institutes. Pharmacological research is defined very broadly and includes, for example, research on cells, cell receptors, and the genetic control of cytoplasmic enzyme expression. The goal of the PRAT Program is to develop leaders in pharmacological research.

Question: Since you aim to develop pharmacologists for work in industry, to what extent does the private sector contribute to the Program?

Answer: A recent analysis of PRAT alumni from the classes of 1965 through 1976 indicates that only 14 percent are currently working in industrial positions, with the vast majority working in universities, at medical schools, and at the National Institutes of Health. While industry does not contribute specific funds to support the PRAT Program, alumni currently with industry have served as consultants and seminar speakers and generally decline reimbursement of their expenses from government funds.

TRAINING PROGRAMS

Question: Your Institute supplies about two-thirds of NIH's support for predoctoral research trainees, and about one-third of NIH support for all trainees. You are clearly a major source for research training.

Yet the January budget proposes to reduce your number of new awards from 109 in FY 1983 to 18 in FY 1984. In new institutional awards, you would be reduced from 130 to zero. Competing renewals also take a beating.

What does this do to your research training program?

Answer: As a result of both fiscal constraints and the NIH policy of maintaining a primary emphasis on the funding of investigator-initiated research project grants, the National Institute of General Medical Sciences' FY 1984 budget shows a decrease in the number of trainees to be supported on both new and renewal training awards. This will mean that the flow of new young biomedical research scientists into the training programs funded by NIGMS will be slowed.

Question: What are the implications of this for basic research which is your major product?

Answer: On the average, it takes 8-10 years from the time an individual enters research training to the time he develops a fully productive career. Therefore, the impact of the entrance in FY 1984 of fewer talented graduate and post graduate students into NIGMS-supported training programs will probably be felt some time in the future, when the pool of well-trained new investigators prepared for research careers will become somewhat smaller. Because it is frequently these new investigators who bring to biomedical research fresh ideas, approaches, and techniques, both basic and applied fields of study will be affected to some extent.

Question: How does your minority training program fare under the budget?

Answer: Under the FY 1984 budget, the Minority Access to Research Careers (MARC) Program is reduced roughly $800,000 below its 1983 funding level. Nevertheless, this program retains its share (about 12%) of both the total NIGMS-supported trainees and the total NIGMS training budget. The FY 1984 reductions in the MARC Program are, therefore, in line with those sustained overall in the NIGMS training budget. It should also be noted that, as a special exception to the NIH policy of providing only 50% of so-called "institutional allowances" for training awards, MARC Program awards receive

100% of these allowances--also referred to as "trainee-related expenses."

ARTIFICIAL SKIN

Question: Doctor, I believe the Institute is supporting research in the development of artificial skin which could be used for burn victims.

Please bring us up to date on your progress particularly as to whether the artificial skin is working.

Answer: As reported last year, Dr. I. V. Yannas of MIT and his colleague, Dr. John Burke, director of the NIGMS burn research center at the Massachusetts General Hospital, have designed an artificial skin for use in the treatment of severe burns. The aim of their work has been to develop a non-antigenic membrane, closely resembling real human skin in its structure and chemical composition. The result has been a two layered membrane, which physiologically resembles the top layers of normal skin. The epidermal, or upper portion, is a homogeneous layer of silicone, 1/10 mm thick. The dermal or lower layer is a preparation of cow-hide collagen and collagen from shark cartilage. The silicone in liquid form is applied in a bacterial-free fashion to the sterile artificial dermis. This skin is then stored in sterile polyethylene bags, ready for use as needed. The shelf life of this skin is extensive.

So far, Dr. Burke has applied this skin to over 40 patients who have had burns ranging from 60 to 95 percent of their total body surface (TBS). The patients ranged in age from 3 to 60 years. As much as 60 percent of the TBS of each patient was covered with the artificial skin and the take on the excised wound bed in each case was 100 percent. Clinically, healing has occured without inflammatory contracture or rejection. The patients have been followed up since the technique was started in 1979, and the long-term clinical and functional results appear to be good to excellent.

Question: To what extent do you actually use healthy skin cells from burn victims in the development of the artificial skin?

Answer: To date, the use of healthy skin cells from burn victims in the artificial skin has been applied only in animals. Research in this area is referred to as "Stage II." Currently, the investigators are concentrating their research efforts in Stage II to attempts to reduce the time of skin enclosure, to avoid the use of autografts for epidermal growth, and to reduce contracture and deep scarring. The investigators feel that they are now near the point where application to humans is possible.

Question: How much are you spending on this research...and when will it become useful for the general public?

Answer: In FY 1983, the National Institute of General Medical Sciences is spending roughly $12 million on trauma and burn research, of which about $230,000 is allocated to the development of an artificial skin by Drs. Yannas and Burke. An additional $60,000 has been awarded to another grantee at the University of Colorado, who is also performing state-of-the-art research in this area.

The use of Stage I artificial skin is currently limited by the quantities that can be produced in Dr. Yannas' laboratory. The

investigators are now awaiting Food and Drug Administration approval of the quality of the skin which is being produced by a commercial laboratory. Once approval from the FDA is obtained, the skin should soon become available to clinicians. Stage II artificial skin is approaching the point where it will be tried on humans. The investigators predict from their work on animals that Stage II skin will be a significant improvement over Stage I skin, which is itself a significant advancement in methodology for treating burn wounds.

PROTECTING THE INVESTMENT

Question: At a time when many budgets are going down, Congress has been increasing funding of the National Institutes of Health, including your Institute. We are concerned that these scarce resources be carefully and effectively used and that there be no basis of criticism of your management of this money.

What assurances can you give us that your Institue is making careful and effective use of the appropriations we provide you?

Answer: We have put great emphasis on hiring a very competent, conscientious, and well-trained staff who see it as their primary goal to assure that our funds are used to support the best research in the most appropriate way. Our business management staff carefully examines each grant before an award is made to make sure that past fiscal performance was adequate and that future expenditures are properly justified and all necessary documentation is provided. Explanations and justifications are sought, whenever discrepancies or unusual circumstances are noted. Our scientific staff is diligent in monitoring the peer review process to make sure that we receive the best possible advice on the scientific merit of applications. In addition to keeping their own scientific skills up-to-date, the staff freely consults with other scientific experts to get additional information on the merits of applications or the opportunities in particular areas of research. All grants that we award thus are scrutinized at many levels, not only for their scientific quality but also for the appropriateness of the budget that is awarded. We strive to fund the most innovative and creative research in the basic biomedical sciences because we feel such research is most likely to provide the new information and the novel ideas that will form the basis for future progress in medicine.

Question: Aside from the peer review system, what institutional arrangements do you have that serve to deter waste, fraud, or abuse in the handling of Federal funds?

Answer: The National Institute of General Medical Sciences feels that our primary defense against waste, fraud, and abuse is a well-trained, conscientious, and vigilant staff. Our staff is on the look-out for problems and frequently communicates with grantees to seek clarification when there are questions. If we uncover suspicious circumstances, or if such circumstances are brought to our attention by others, they are referred to the Division of Management Survey and Review, Office of the Director, National Institutes of Health, for careful investigation.

INSTRUMENTATION PROGRAM

Question: You have a popular program to provide groups of investigators with complex and expensive instruments to share in their work. This is the Shared Instrumentation Program.

How many scientists and how much money is allocated to this program?

Answer: From FY 1979 through FY 1983, the NIGMS made approximately 100 awards through this program at a total cost of approximately $11 million. These awards directly benefited approximately 400 scientists who represent the major users of this equipment. For FY 1984, approximately 20 awards are planned at a cost of about $3 million, an increase of $2 million over FY 1983. These would directly benefit an estimated 80 scientists who would use these instruments in their research projects. It should be noted that these shared instruments are also available to young scientists for feasibility studies and preliminary investigations.

Question: The Division of Research Resources also funds a similar program which we said should be expanded. Is there coordination between your programs--or, do you run into problems of overlap and duplication?

Answer: The staff of the two programs work closely together in all phases of the award process: communications with scientists in the field, assignment of applications, review, and preaward planning. By working closely in this way, the programs work in a complementary fashion and avoid overlap and duplication. Both programs also coordinate with similar programs in other government agencies (e.g., NSF and the Department of Defense).

MINORITY ACCESS TO RESEARCH CAREERS

Question: NIGMS is one of the two Institutes with primary responsibility for developing minority participation in the biomedical sciences (Research Resources is the other). Although ethnic minorities are still not active in research in proportion to their numbers in the general population, NIGMS has proposed to reduce its financial support for this program from $6.3 million to $5.5 million, despite increases in most other areas. Does this indicate the program has been so successful that efforts in this area can be cut back?

Answer: Like all of the training programs funded by NIGMS, in FY 1984 the Minority Access to Research Careers (MARC) Program will experience a reduction in funds. Because the MARC Program supports only training grants and not research grants for which, in the other NIGMS programs, some funding increases are proposed, the proposed reduction for the MARC Program from FY 1983 to FY 1984 is more apparent. However, the NIGMS commitment to this program remains strong. A high proportion (85%) of graduates of the MARC Honors Undergraduate Research Training Program are pursuing graduate training in the biomedical sciences or in professional schools. Furthermore, a significant number of faculty fellows (89%) have completed advanced research training and have returned to minority institutions. Because of these gratifying results, the Institute proposes to continue to devote about 12% of its training budget to support MARC awards. The $5.5 million for the MARC Program in FY 1984 will sustain its various high quality training activities and, hopefully, contibute further to the pool of minority scientists pursuing research careers.

SUBCOMMITTEE RECESS

Senator WEICKER. The subcommittee will stand in recess until tomorrow morning at 8:30 when we will meet again in this room to continue hearings on the fiscal 1984 budget requests of the National Institutes of Health.

Thank you very much.

[Whereupon, at 12 noon, Tuesday, April 12, the subcommittee was recessed, to reconvene at 8:30 a.m., Wednesday, April 13.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1984

WEDNESDAY, APRIL 13, 1983

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, D.C.

The subcommittee met at 8:30 a.m., in room SD-116, Dirksen Senate Office Building, Hon. Lowell P. Weicker, Jr. (chairman) presiding.

Present: Senators Weicker and Proxmire.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

STATEMENT OF DR. MORTIMER B. LIPSETT, DIRECTOR

ACCOMPANIED BY:

JOEL R. HEDETNIEMI, EXECUTIVE OFFICER, NICHD
DR. JAMES B. WYNGAARDEN, DIRECTOR, NIH
H. RICHARD MILLER, ASSISTANT DIRECTOR FOR BUDGET, DIVISION OF FINANCIAL MANAGEMENT, NIH
ANTHONY ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET, DHHS

BUDGET REQUEST

Senator WEICKER. We resume the fiscal 1984 NIH hearings this morning with the testimony on the Institute of Child Health and Human Development.

The revised 1984 budget request for the Institute is $256.5 million, which is slightly under the January budget request, but $2.9 million above the fiscal year 1983 level.

Here to testify in behalf of the Institute is Dr. Mortimer B. Lipsett, the Director.

Now, what I would like to do prior to specifically getting into the National Institute of Child Health and Human Development is to allow Senator Proxmire, who was attending other hearings yesterday, to have a chance to propound the questions that he had for Dr. Wyngaarden.

So if we could start off in that manner and then go to Dr. Lipsett's testimony.

Senator PROXMIRE. Thank you very much, Mr. Chairman. I very much appreciate that. I made the mistake of stumbling in here at this hour yesterday only to find that the hearings started at a later hour. Lowell is the earliest rising chairman in the Senate.

NONCOMPETING RESEARCH PROJECT GRANTS

Dr. Wyngaarden, one trend that seems quite clear over the past few years is the increase in noncompeting projects while competing projects have remained more or less constant.

For example, between 1982 and 1983, noncompeting projects increased by 500, about 4.5 percent, while competing projects dropped by 113, about 2.2 percent. Wouldn't it make sense to try to reverse this trend in your attempt to search out the most innovative approaches to the prevention and cure of disease?

Dr. WYNGAARDEN. Thank you, Senator.

Perhaps I can explain how that takes place. The noncompeting portfolio increases in relation to the number of competing awards in previous years. Prior to about 1980, there was a great deal of fluctuation in the number of competing awards that were made in a given year. They ranged, for example, from 2,600 during one year to 5,900 in another.

The NIH made an attempt to stabilize the awarding of new and competing grants progressively. This became articulated as policy in about 1980. Thus, in each of the last few years, we have funded about 5,000 new and competing awards.

Funding for new and competing grants increases the number of noncompeting in subsequent years. The average award runs for about 3 to 3½ years, with some as long as 5 years. That trend should level out as we fund a more nearly constant number of new and competing awards each year.

It is important, as your question implies, to make certain that there is an adequate opportunity for new scientists and new ideas to come into the system each year. The administration's attempt to stabilize the new and competing portfolio at about 5,000 per year speaks to that.

On the other hand, the noncompeting research is also extremely important. Established scientists are highly productive year after year, in the later as well as the initial years of the award.

Senator PROXMIRE. Perhaps I am confusing this with defense procurement or some other area that isn't comparable, but I feel that competing awards usually give whoever is making the buying a better opportunity to get higher quality at lower price. Competition provides an advantage.

For instance, in 1984, I understand you will be funding over twice as many noncompeting projects as competing projects. What would be the result if you required 10 or 20 percent of your noncompeting projects to compete for further funding? Can you do that?

Dr. WYNGAARDEN. Each noncompeting award was a competing award in the previous year or two. There are no noncompeting awards that don't go through initial peer review.

Senator PROXMIRE. Each noncompeting award is simply an award that was previously a competitive award?

Dr. WYNGAARDEN. Yes, sir.

Senator PROXMIRE. Each of them?

Dr. WYNGAARDEN. Every last one.

Senator PROXMIRE. You have no awards that are not based at least initially on competition?

Dr. WYNGAARDEN. That's right.

Senator PROXMIRE. Do you ever review extensions to see if it would be possible to open them up to competition?

Dr. WYNGAARDEN. We do that. A noncompeting award is one that might have been awarded, let's say, as a competing award in 1981. It becomes noncompeting as it is refunded in 1982 and 1983. Each year, however, the investigator must file a project progress report which is reviewed by staff.

If the award is made for 3 years and that investigator wishes to continue the project, he or she must come back in for a competing renewal of that award. The noncompeting grant is a continuation of the same project that went through peer review in a previous year.

[The information follows:]

NONCOMPETING AWARDS

On reflecting further on your question about noncompeting grants it occurred to me that there may be some misunderstanding about the use of the term which suggests an analogy to a noncompeting contract. NIH's use of the term noncompeting award refers to the payment of cost of the continuing years of a multiyear award. Most research projects are awarded for 3 or 4 years after a thorough multiphase review process in which they compete against other applications. Hence, during the first year of the award they are called competing projects. In subsequent years, they are called noncompeting because they do not go through the same searching review until they come up for renewal.

INCREASE OVER 1983 BUDGET

Senator PROXMIRE. Now, Dr. Wyngaarden, one of Harvard medical school's recent newsletters states, and I quote:

> Today, as deaths from infectious diseases continue to decline, there is a great need for information on such chronic conditions as hardening of the arteries, high blood pressure, and arthritis—diseases from which millions suffer.

If that is the case, why are you holding the Heart, Lung, and Blood Institute to a 2.4-percent increase? Wouldn't it make more sense to provide some more generous increase? It seems to me, 2.4 percent is probably an actual decline if you allow for inflation.

Dr. WYNGAARDEN. The total increase for the NIH budget this year is 1.8 percent. Therefore, because of the constraint of the budget, no institute is showing substantial growth. There are minor fluctuations among the various institutes to reflect differences in their commitment bases from previous years.

There is not much flexibility in this area. The increase for the National Heart, Lung, and Blood Institute is slightly more than the average because of commitments it has with respect to previous decisions.

Senator PROXMIRE. Wouldn't you agree that the Heart Institute would suffer an actual decline in real terms?

Dr. WYNGAARDEN. Yes; we expect that there will be a decline. And that is, of course, the reason for belt tightening all along the line.

Senator PROXMIRE. Your overall increase, then, is 1.7 percent? Is that what you say?

Dr. WYNGAARDEN. The increase is 1.8 percent over the continuing resolution of 1983.

Senator PROXMIRE. That means an even more severe decline.

Dr. WYNGAARDEN. Yes.

REQUEST TO OMB

Senator PROXMIRE. Was this budgetary constraint imposed by OMB?

Dr. WYNGAARDEN. This is the President's budget for 1984 which takes into consideration the full range of Federal commitments. We are working within the President's budget.

Senator WEICKER. What was your request to the Office of Management and Budget? Was it higher?

Dr. WYNGAARDEN. Yes; it was higher.

Senator PROXMIRE. Can you tell us what it was?

Dr. WYNGAARDEN. Yes; the Department's estimate to OMB was $4.078 billion.

Senator PROXMIRE. So they cut the increase in half, roughly.

Dr. WYNGAARDEN. The President's budget is $4.077 billion.

Senator PROXMIRE. I beg your pardon. I was thinking of a different figure.

What was the request you made for the Heart, Lung, and Blood Institute?

Dr. WYNGAARDEN. The request to OMB was $620 million.

Senator PROXMIRE. What is that in percentage terms?

Dr. WYNGAARDEN. Percentage with respect to what base, sir?

Senator PROXMIRE. Well, the Heart, Lung, and Blood Institute increase approved by OMB was 2.4 percent. That is the figure I am using for comparison.

Dr. WYNGAARDEN. That was essentially the same as the 1983 budget.

Senator PROXMIRE. OMB is allowing you a 2.4-percent increase. My question is, how much of an increase did you request in percentage terms?

Dr. WYNGAARDEN. The request to OMB did not contain an increase for the Heart Institute this year.

Senator PROXMIRE. So you got what you requested?

Dr. WYNGAARDEN. Yes.

BUDGET PROCESS

Senator PROXMIRE. Why didn't you request more in view of the need as stated in the Harvard newsletter?

Dr. WYNGAARDEN. I believe Mr. Itteilag wants to answer that question.

Mr. ITTEILAG. Senator, there is an important technical budgetary fact that needs to be brought out here. At the time the Department's budget was submitted to OMB, Congress had not completed action on the fiscal 1983 budget. Therefore, we based our submission to the Office of Management and Budget on the President's fiscal year 1983 budget.

Subsequent to that time, the Congress completed action on fiscal year 1983 appropriations and with respect to NIH added in the range of $255 million to the 1983 budget base.

The addition of that magnitude of funds increased the grant continuations, if you will, that NIH carries into the 1984 budget, and, in effect, made the fiscal year 1984 request to OMB out of date.

However, the debate that subsequently ensued within the executive branch over the funding level of NIH did not yield any increase in total resources at NIH, notwithstanding congressional action which increased the fiscal year 1983 base.

[The information follows:]

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

With regard to the budget request for NHLBI in particular, it should be pointed out that the President's budget request for fiscal year 1983 was $577,143,000. Based on that amount, the request to OMB for fiscal year 1984 was $620,261,000. Subsequently, the passage of the continuing resolution for fiscal year 1983 provided a level of $622,745,000 for NHLBI. It is for this reason that the 1984 request to OMB ultimately did not reflect an increase over the 1983 level. The revised request for 1984 is $637,738,000, an increase of $14,993,000 or 2.4 percent over the 1983 continuing resolution.

INDIRECT COSTS

Senator PROXMIRE. Dr. Wyngaarden, as you indicate on page 3 of your justification, the level of indirect costs on research grants as a percentage of total costs has increased from 20.6 percent in 1972 to about 30 percent in 1982—an increase of approximately 10 percent over the last 10 years.

One suggestion for controlling Federal indirect cost payments has been to limit them to some sort of historical average. This would reward the institutions that have done a good job in controlling their indirect costs and penalize the institutions that have done a poor job.

Why wouldn't this be a good way to limit indirect cost growth?

Dr. WYNGAARDEN. That, sir, is indeed our recommendation. We have prepared a report for the committee on indirect costs, including several options that might be addressed for containing them.

Senator PROXMIRE. Can you make that recommendation available to our staff?

Dr. WYNGAARDEN. Yes; we have submitted a report.

Senator PROXMIRE. Our staff wasn't aware that you had made that proposal.

Dr. WYNGAARDEN. Yes, sir. I think it was released about 1 day ago.

Senator PROXMIRE. Now, as I am sure you know, the National Science Foundation indicates on each grant award the amount of the grant that will be dedicated to indirect costs. By contrast, NIH provides each

school each year a lump sum amount for indirect costs computed on the basis of total grants awarded.

The virtue of the NSF approach is that it lets each principal investigator know how much of his grant award is devoted to costs only indirectly connected with his research. If he and his colleagues are distressed about the extent to which their grant funds are being eaten up by indirect costs, they can apply pressure on the school administration to hold down or review these costs.

Why isn't this a good reason for NIH to include indirect costs as a portion of each grant award?

Dr. WYNGAARDEN. It is included, sir. The grant award has both a direct and indirect component. The direct cost represents those expenditures that are most easily associated with the project. Indirect costs include a variety of other expenses not so closely associated.

Senator PROXMIRE. Is that information on the grant award sheet that goes to each investigator?

Dr. WYNGAARDEN. I will have to ask.

Senator PROXMIRE. Could you locate that information?

Dr. WYNGAARDEN. Dr. Raub, our Deputy Director for Extramural Research and Training, will respond.

Dr. RAUB. You are correct, Senator; the amount is not provided via the grant award sheet. The moneys are pooled into a separate system called the indirect cost management system, and provided, as you indicated, via a separate award mechanism. Each investigator is able to determine readily the amount of indirect costs associated with the award because the percentage is known.

Senator PROXMIRE. Why not put it on the grant award sheet so it is clear? Then the comparison would be automatic.

Dr. WYNGAARDEN. My experience years ago was that it was on the award, but I don't know what the current practice is or why it was changed.

Senator PROXMIRE. Perhaps you can look into that and let us know, if you would.

Dr. WYNGAARDEN. I will be glad to.

[The information follows:]

INDIRECT COST MANAGEMENT SYSTEM

In 1968, a DHHS (then DHEW) study group of the Grants Administration Advisory Committee concluded that centralization of indirect cost payments to grantee institutions was feasible and recommended that it be tried on a pilot basis. The system was designed to provide for the removal from the individual program activities the responsibility for the calculation, adjustment, and final settlement (closeout) of indirect costs and instead place the overall responsibility and management of such a system in a single focal point. Questions posed to grantee institutions during the pilot phase resulted in overwhelming support (a ratio of 3 to 1) for separation of indirect cost allowances from the notice of grant award so that less time would be involved by principal investigators reviewing overhead costs over which he or she essentially had no control.

On July 1, 1971, the indirect cost management system (ICMS) was established as a centralized system for NIH. In 1973, the DHEW Audit Agency issued a report which stated that the ICMS had made substantial progress toward implementing the concept of a centralized indirect cost management system for NIH and that this "has substan-

tially reduced the administrative effort associated with indirect cost matters for both NIH and the grantees." In subsequent years, NIH has frequently heard from grantee staff that the indirect cost system operated by NIH was preferable to that employed by any other Federal granting agency.

CONSULTANT SERVICES

Senator PROXMIRE. Finally, and this is my last question, information supplied by the Department indicates that the cost of consultant services paid for by the National Institutes of Health will increase by about one-third between 1982 and 1984 to a total of $23.9 million in the coming fiscal year.

Can you tell us why consultant costs have gone up so dramatically?

Dr. WYNGAARDEN. We have 105 committees of extramural consultants that assist in the peer review process. Primarily, they serve as advisers to the various institutes.

During the past decade, the number of grant applications has greatly increased. Therefore, the work of our study sections has dramatically increased. We have from time to time chartered additional study sections to keep pace with the developments in the field of science.

Senator PROXMIRE. Have grant submissions increased proportionately? $23.9 million seems a very large increase for consultants. It is a one-third increase.

Dr. WYNGAARDEN. Grants have essentially doubled within the decade.

Senator PROXMIRE. I am talking about the increase occurring between 1982 and 1984. That is only 2 years.

Dr. WYNGAARDEN. I would have to review that and provide the answer for the record, sir.

Senator PROXMIRE. Can you do that?

Mr. ITTEILAG. Senator, let me on this matter also interject that in fiscal year 1982, because of the fact that we had four continuing resolutions and other factors that caused a great deal of uncertainty in what ultimate spending levels were going to be, caused us to restrain expenditures in a number of discretionary areas such as consultants and travel, for example, two of those.

So that, I think, is part of the material that we provide for the record.

It might be well to also include some fiscal year 1981 numbers because I think that probably represents a better base from which to make judgments about the fiscal year 1984 levels. We can do that.

[The information follows:]

CONSULTANT SERVICES

The increase in consultant services from $17.9 million in fiscal year 1982 to $23.9 million in fiscal year 1984 is basically in two areas: support of advisory committees, and program evaluation activities. The advisory committee category includes the institutes' national advisory boards or councils, boards of scientific counselors, program advisory committees, grant and contract review committees, and Division of Research Grants study sections.

The increase in this category over the 2-year period, which is $3.4 million, is due to several factors: a continuing increase in the number of research project grant applications being received; a large number of vacancies on the advisory committees which are now being filled; and the chartering of additional study sections in order to keep pace with developments in rapidly expanding scientific fields.

The program evaluation portion of consultant services increases from $3 million in fiscal year 1982 to $5 million in fiscal year 1984. These funds, in accordance with section 513 of the PHS Act, are to be used at the discretion of the Secretary, DHHS, for the evaluation of health programs. Such evaluation studies assist in program development and management decisionmaking.

STATEMENT OF DR. LIPSETT

Senator PROXMIRE. Thank you, Mr. Chairman.

Senator WEICKER. Thank you, Senator Proxmire.

In the first round of questions to Dr. Lipsett, which will be very much the same as the questions that were asked yesterday except in the specifics that apply to his Institute, I would appreciate the other Directors listening carefully to the questions. We can save time here in our presentations after you get through with your comments as you prepared them, if you go directly to responding to the questions which will be propounded here.

I know the temptation well, having sat and waited my turn at hearings, while you are waiting your turn, you tend to nod off.

Dr. Lipsett, please proceed with your presentation. We are looking forward to it.

Dr. LIPSETT. Thank you, Mr. Chairman.

May I present Mr. Hedetniemi, the Executive Officer of the Institute.

Some 20 years ago, the Congress established the NICHD as a noncategorical Institute. As I am sure you and Senator Proxmire know, we have a very broad range of responsibilities. The Institute's mission includes the processes of conception, fetal development, every aspect of pregnancy, delivery, and the perinatal period. We study the growth of children—physical, mental, and behavioral—on through adolescence. The mission encompasses all aspects of reproduction, including fertility, infertility, and contraception. We also study population dynamics—what goes into the process of deciding to have children, when, and how many—and issues that affect population as a whole, for example, what are immigration and other demographic changes doing to the structure of families and to the needs of children.

So throughout the Institute, we stress not only child health, but the entire process of human development.

Now, I would like to highlight just a few points that illustrate the depth and the diversity of the research program of the Institute and then to answer your questions.

REPRODUCTIVE BIOLOGY

One particularly fascinating area takes us back to the early 1960's when it was first proposed that the brain controlled the functions of the pituitary gland and, through this gland, the reproductive processes.

In 1977, two of our grantees received a Nobel prize for isolating from the hypothalamus, an area of the brain, the materials that actually control reproductive processes. In the few years since these materials have been isolated chemists have produced synthetic modified copies of these materials. These materials now are being used:

One, to develop male and female contraceptives;

Two, to stimulate ovulation in infertile women;

Three, to deal with several diseases affecting the reproductive health of women such as endometriosis and polycystic ovarian disease;

Four, to treat boys and girls who develop sexual changes very early in life, a condition known as precocious puberty.

Today, these materials after some 20 years of basic research are rapidly taking their place in clinical medicine.

Another exciting area which is perhaps 10 or 20 years from realization is gene transfer. Both our intramural and extramural scientists have achieved this in laboratory animals.

We have so much to learn about this entire process, but the vision of what lies ahead is going to mean that progress in this field will be very rapid, attracting some of our best researchers in molecular biology, cell biology, and genetics.

PREMATURITY

Two of the leading causes of death in infancy are prematurity—that is, babies born too soon or too small, and birth defects. These are the two main causes.

We have a large investment in research on prematurity. We are supporting some clinical trials designed to prevent prematurity, and a very large group of studies on the entire question of birth defects.

Many of the things that you heard yesterday having to do with recombinant DNA techniques, our ability to map genes, and the use of monoclonal antibodies, are being applied in this particular area.

MENTAL RETARDATION

Mental retardation is another area for which the Institute has primary research responsibility. We know that some 6 to 7 million people, depending on definition, suffer from mental retardation.

We have an extensive program in neurobiology, genetics, and behavioral sciences that deals with this complex problem.

One recent accomplishment is finding that intelligence is plastic. People with mental retardation are not static; performance can be improved.

My assessment of the science dealing with the relationship between neurobiology and behavior is that we stand now where we stood with cancer 25 years ago. We now have the tools and are beginning to look at what is happening in the architecture of the brain and to relate that to behavior. That is a very recent accomplishment which will take many years to pay off. But it is a very real beginning.

BEHAVIORAL SCIENCE

Our Institute has the principal NIH responsibility for research in behavioral science. How does behavioral science work? What techniques ought to be used?

We have a large investment in the use of behavioral science in studying how children develop, how they learn to read, and how they develop cognitive processes. The study of risk-taking behavior is important because of its direct preventive aspects. What is it that makes teenagers smoke or drink? Why do the teenagers who engage in sex early not use contraceptives when they know about them?

There is a whole series of important questions that influence adult life and behavior that are being studied in terms of basic elements of behavioral science.

CONTRACEPTIVE EVALUATION

We have a continuing important program in contraceptive evaluation. NICHD-supported surveys showed that the pill decreases the chance of getting ovarian and uterine cancer and does not increase the risk of breast cancer. This was not known a few years ago.

These are valuable findings because they allow women in our population to make informed choices about their method of family planning.

These are very brief outlines of a few of the highlights of the Institute.

Senator WEICKER. Why don't I go through this question scenario so others can pick it up and have you respond to it.

Dr. LIPSETT. All right.

PRICE FOR 5,000 NEW GRANTS

Senator WEICKER. We are interested in getting some perspective on the administration's price for 5,000 new and competing grants since the budget proposal does not include the additional funds needed for such a level.

Instead, the revised budget proposes to put together an extra $140.9 million for this purpose by taking it away from other NIH activities. For example:

One, noncompeting continuation awards would be cut $17 million.

Two, specialized and comprehensive centers would be reduced $49.2 million.

Three, biomedical research support awards would be cut by $24.7 million.

Four, targeted research would be reduced by $20.2 million.

And five, there would be other cuts, including reductions in training, for an additional total of $29.8 million.

All of this adds up to a total of $140.9 million. Here are the questions that I am going to ask—and I will go through the whole thing, and you can answer in its entirety:

How do you view the activities proposed for reduction—as integral to the NIH program, or as separate from it or even as expendable?

What clinical trials won't be done, or will be postponed, as the result of these cuts?

What effect will this roller-coaster approach to funding have on those contemplating careers in biomedical research?

Now, additionally, there are effects as well, not just the cuts I have already referred to, but there are other effects.

For example, the January budget first, now the April budget, assumed cuts in the average award for new and competing grants below what the full average cost should be. For new grants, this appears to be a difference of some $17,800, or $142,400 for the full cost versus $124,600 in the revised budget.

How will this reduction of the average cost of grants affect your Institute? And most importantly, to what extent will it change the scope and quality of the projects that are reviewed by your study sections?

The same applies in the area of the noncompeting continuation grants where they are projected to decrease by $12,400 below the full average cost.

Again, what effect will this reduction have on your Institute and what will this do to the scope and quality of the projects that are reviewed by your study sections?

Dr. LIPSETT. Thank you, Mr. Chairman.

I think that I share with the other Institute Directors my conviction that our support of investigator-initiated research, whether it be extramural or intramural, is our highest priority. Nevertheless, within NICHD, research is integrated among the various mechanisms.

The centers work with many of the grantees who carry out research on their own as well. Some reduction in the centers line will inevitably affect the research mission of the Institute.

Now, with respect to clinical trials, we would not be able to fund six new clinical trials. Two of these have to do with the prevention of prematurity. We would not be able to fund eight of the nine research center grants due for renewal in 1984. They are centers in population research, reproductive biology, and in mental retardation.

You asked about the roller-coaster effect.

MENTAL RETARDATION CENTERS

Senator WEICKER. I did have one question there. The mental retardation centers, the University of Wisconsin, University of Chicago, and Vanderbilt, what do they do?

Dr. LIPSETT. The Wisconsin center does mostly neurobiology. They also have a large section in behavioral medicine. In Vanderbilt, it is mostly behavioral medicine.

The University of Chicago is perhaps best known for research on brain chemistry as related to mental retardation.

Senator WEICKER. Go ahead.

Dr. LIPSETT. The roller-coaster effect is particularly difficult for physicians planning to enter research. They know very well the lack of stability of support for research. Inevitably, they see that as a detriment to their careers in medical research and I feel that this is one of the significant factors that prevents more young physicians from entering medical research. In research training, the NICHD would support 554 training positions in 1984 compared to 570 in 1983.

With respect to your last question about the average cost and reduction in the average cost of competing and noncompeting grants, there is, of course, some point at which any investigator will not be able to do what he has proposed he wants to do when you cut his budget sufficiently. The average cost of noncompeting and competing research project grants would be reduced by $8,900 and $8,100, respectively.

We do have flexibility in the Institute programs to make decisions based on investigator needs and so on.

DOWN SYNDROME

Senator WEICKER. We know that congenital defects are a major cause of mental retardation in infants. As I understand it, prior to my taking the chairmanship of the subcommittee, the subcommittee has been interested in your efforts to develop an animal model for the specific chromosome thought to be most responsible for Down syndrome.

Would you indicate to the committee what use is being made of this model, and will it accelerate research on Down's?

Dr. LIPSETT. The model is now being made available to investigators throughout this country and abroad and is being used in research studies relevent to Down syndrome. We now know that trisomy 16 is similar to human trisomy 21. That is, the same chromosome in the mouse contains at least four of the same genes that are on the human chromosome.

Future development of the model would be to look at the biochemical and even behavioral aspects of this and then begin to see if you can relate behavioral aspects to what is happening with respect to gene effects of this particular chromosome.

This animal model will be the primary source of experimental material to be used in several projects in a newly established Mental Retardation Research Center giving specific research emphasis to Down syndrome. The animal model will facilitate studies that are otherwise difficult or unethical to perform on human subjects.

Senator WEICKER. Let me say this: My Down's child was born a little over 5 years ago. And I was quite surprised as to the lack of any consensus as to what to do. Some people were advocating vitamin therapy, and other people were advocating other methods.

Fortunately, I think we are in excellent hands with Dr. Rosenbaum at Children's Hospital.

But all I am trying to say is I really got the feeling that there really wasn't much information—I don't know what the scientific terms are—as to how this comes about. We have gone a long way, true, in how we come at these children, for example, you mentioned early intervention in terms of education, et cetera, and that we have done well with it.

I just had the feeling still nobody knows much about how it happens. They know what happens, but they do not know what to do about it.

Dr. LIPSETT. You are certainly right, Senator. The relationship between the neurobiology and behavior is, as I mentioned, one of the exciting areas of research. We don't know much about it yet, but we are

now beginning to get clues in a number of animal models, only one of which is related to Down syndrome, but a number of which are related to behavior.

One can now test in monkeys and in rats relations between central nervous system physiology and architecture and behavior. The program of trying to understand what happens to the gene, how that affects central nervous system architecture, and what the behavioral results are later, redound to the study of not only Down syndrome, but fragile-X syndrome and the whole category of genetic defects that are associated with mental retardation.

DOWN SYNDROME THERAPY

Senator WEICKER. One last question in this area because I don't mean to focus on my personal inquiries, but you mentioned there are those that feel there is a betterment in the condition achieved through vitamins. There are others that indicate nutrition can correct this condition, et cetera.

What worries me is my understanding, unless I am the one that is off base, that this is really all very speculative indeed. It can achieve many things, but there are a lot of parents for some reason or other who get gulled into feeling the condition can be changed by this type of approach.

I would like to have your comment on that.

Dr. LIPSETT. Yes; I would agree with your characterization that this area is speculative. Wherever good clinical trials have been carried out, no differences have been found.

PREMATURITY

Senator WEICKER. One other question, and I will turn it over for any specific questions to Senator Proxmire.

Premature birth is an important factor in infant mortality. Of the 45,000 infants who die in the United States each year, about two-thirds are premature babies born too small, too soon.

In order to prevent prematurity, you apparently need to know more about what starts premature labor. It is surprising that we don't know all we need to know in this field. Why is there this knowledge gap?

Dr. LIPSETT. It is a tough problem for many reasons. For one, it turns out that the animal models that people have been using—sheep, for example—to study this in detail do not have the same stimuli for the onset of labor as occurs in humans.

We have some new leads—one at the University of Texas is particularly promising toward understanding the cascade of hormonal events that lead to the initiation of labor. Once onset of normal labor is clarified, appropriate interventions to prevent premature labor could be achieved.

We would like to be able to prevent premature births because that is a major problem, not only for mortality, but for morbidity as well.

GENITAL HERPES

Senator WEICKER. How serious is the current wave of genital herpes infections to newborns?

Dr. LIPSETT. It presents a known risk to the newborn. I would like to ask Dr. Krause to answer that further.

Senator WEICKER. Dr. Krause?

Dr. KRAUSE. Genital herpes when present in the genital tract of the female is a risk to the newborn. The risk is the possible development of herpes encephalitis, which is a very fatal disease. And, therefore, the usual recommendation, which is followed by most, is that the baby be delivered by cesarean section.

One of the targets for a herpes vaccine will be the immunization of individuals in the hope of eradicating that infection which is indeed a risk for the newborn.

Senator WEICKER. Are we close to the development of a herpes vaccine either for type I or II?

Dr. KRAUSE. The herpes vaccine is one of the candidate vaccines on our accelerated development of new vaccines list. It is one of the 10 I hope that we will make tremendous progress on in the next decade.

The molecular biology approach for an attenuated live vaccine for genital herpes, it seems to me, is very promising. There are some very important leads now that are being followed by investigators in various parts of the country. And I would be very surprised if we did not have a vaccine which we were testing in a preliminary way within several years. The drug industry is currently testing a killed herpes virus vaccine.

Senator WEICKER. Am I correct that when the herpes problem first came to wider attention than just the medical community several years back, that there were those that said it was related to the smallpox virus. Is that true or not? And if so, why wouldn't we be farther along in the development?

Dr. KRAUSE. They are not closely enough related so that what we have learned about developing a vaccine for smallpox would be of help in developing a vaccine for herpes. The problem with the herpes virus is that once you contract it, it becomes latent in your nervous tissue only to be reactivated again.

That is not true of smallpox. Smallpox is a disease which you acquire, and if you recover from it, the virus is eliminated from your body.

So the principles of smallpox vaccination are entirely different from the principles we must look for with herpes.

Senator WEICKER. Senator Proxmire?

RESEARCH CENTERS

Senator PROXMIRE. Dr. Lipsett, how many centers do you fund?

Dr. LIPSETT. Right now, we fund 43 centers.

Senator WEICKER. Is NIH eliminating funding for most research centers that are up for renewal?

Dr. LIPSETT. Dr. Wyngaarden, would you want to answer that NIH question?

Senator PROXMIRE. The Institute also.

Dr. LIPSETT. In order to meet our commitment to investigator-initiated research, we have agreed to eliminate eight of the nine renewals in the research centers' budget.

Senator PROXMIRE. You answered that question a little earlier, I think, with the chairman, but I am talking about that overall. See, I want to get whether or not there is a fair determination here.

It seems to me it is almost a matter of bad luck that a center is to be terminated. If they aren't up for renewal, they escape. Is that right?

Dr. LIPSETT. Yes; in that sense, you are correct, sir.

Senator PROXMIRE. Well, isn't there some way you could judge the performance of all centers and make reductions in this work of those that scored at the lower end of the scale instead of just the ones that are up this year?

Dr. LIPSETT. Well, the centers——

Senator PROXMIRE. I am sensitive on this. As was pointed out, two of these are in my State, two of the nine.

Dr. LIPSETT. The centers do go through peer review as do all of our investigators. We have commitments to centers which are not up for renewal at this time, and these are fairly firm commitments.

The decision was made, based on where we place our highest priority, to retrieve these funds from the centers' budget line.

Senator WEICKER. Look at it on the bright side. We are not really going to reduce and eliminate the centers, but put the money back in to keeping the centers functioning.

Senator PROXMIRE. I am glad we have such a bright side chairman.

Senator WEICKER. Unfortunately, in this seat, the bright side usually results in quite a fight before you are all through.

Senator PROXMIRE. On Wisconsin.

I think this is a question for Dr. Wyngaarden or Dr. Ringler. It has to do with the way you set priorities among the various Institutes.

How did you decide that the National Institute of Child Health and Human Development should receive a 1.2-percent increase in funding while the National Institute on Aging's budget goes up by 5.8 percent?

Dr. WYNGAARDEN. Senator, with the constraints of the current budget, we first looked at the continuing commitments from decisions made in previous years. There isn't very much flexibility this year.

So that an institute that happened to be in the cycle, making more than the average awards last year, would have a higher commitment base this year than another institute might have. And that fundamentally determined the range of increases within the constraints of this particular budget.

Senator PROXMIRE. So you try to keep the amount over a period of years fairly similar, an increase over a period of 3 or 4 years, so that one year might be disproportionate, but over a period of years, it would not?

Dr. WYNGAARDEN. Yes; because of the way budgets are constructed and commitments are made in a given year two institutes might be quite alike in a subsequent year in terms of the commitments that carry forward.

We also take into consideration the developments of the various institutes. And there are times when one is given some priorities over another because of the very exciting lead in that particular institute.

This year, however, most of the minor variations in the increases are consequences of the continuing commitments, of decisions made in the previous years.

Senator PROXMIRE. So that over the last several years, including this coming year, the National Institute of Child Health and Human Development would be treated about the same as the Aging Institute?

Dr. WYNGAARDEN. Oh, yes.

INFANT MORTALITY

Senator PROXMIRE. OK. Then one other question.

You have answered this question in part, but I want to be sure I understand it.

On page 59 of your justifications, you indicate that of all the developed nations of the world, the United States has one of the highest rates of premature birth. Could it be argued—and you have just called this one of the leading causes of death, the fact that a baby is born prematurely—is this a weakness in the generally impressive program being pursued by the Institute? We haven't really been able to make progress?

Dr. WYNGAARDEN. I think, sir, that is a question Dr. Lipsett could handle best.

Senator PROXMIRE. Yes, sir.

Dr. LIPSETT. It is both a medical and a social phenomenon, Senator, that leads to small babies. For example, a very large fraction of the Institute's research is in studying the process of nutrition, the role of nutrition in producing a baby that is of normal size, and the many other factors surrounding development of the baby that contribute to prematurity.

I wouldn't say it is a weakness in the Institute's portfolio of research.

PRENATAL NUTRITION

Senator PROXMIRE. Let me interrupt to say my question is: Why do we do so poorly compared to other countries? Does nutrition have anything to do with this?

Dr. LIPSETT. That is only a small part of it.

Senator PROXMIRE. It is to some extent?

Dr. LIPSETT. It is to some extent because we know from both animal studies and human studies nutrition——

Senator PROXMIRE. I am surprised at that because it would seem to me that our nutrition should be superior. We are a more affluent society. The one thing we have an abundance of and surplus of is food.

Lately, we have been promoting the WIC program and others. And yet, you say that the nutrition is one of the causes of premature birth which in turn results, of course, in infant mortality.

Dr. LIPSETT. Deficits in particular nutrients at specific stages of pregnancy are one of the several causes of small——

Senator PROXMIRE. Other countries are ahead of us in providing a better diet for mothers?

Dr. LIPSETT. It is only one of the many causes, Senator. Another cause in this country is the fact that many of the small infants are born to very young teenaged mothers.

Senator PROXMIRE. More than in other countries?

Dr. LIPSETT. Yes, sir.

Senator PROXMIRE. But you say the first cause; that is something we can do something about that I haven't heard any argument on. We have had a lot of debate and discussion of the WIC program, and it is important. But I don't think people have stressed, at least in my consciousness, as much in preventing premature births.

Dr. LIPSETT. A part of that is not perhaps availability; it is the awareness of our very young teenagers about the sort of food that they should eat during pregnancy. Certain other behavioral characteristics are involved as well.

For example, we know that such things as smoking and substance abuse during pregnancy all bear on this problem of prematurity and small-birth infants. So there are many causes.

TEENAGE PREGNANCY

Senator PROXMIRE. What is the principal social cause for the fact that you say that there are so many young teenaged pregnancies in this country compared to other countries. Why should we be so different?

Dr. LIPSETT. It is an interesting question about which we are proposing several studies and have some information. The reasons for teenage pregnancy are either the lack or misuse of contraception, or for some teenagers, a desire for early pregnancy. This is not really completely understood, but it is an important factor.

Senator PROXMIRE. Other countries have better information systems in which there is better sex education and so forth?

Dr. LIPSETT. I am afraid I couldn't say that they are better. Behavior for whatever the reason is different.

Senator PROXMIRE. Thank you.

Thank you, Mr. Chairman.

PREPARED STATEMENT AND SUBMITTED QUESTIONS

Senator WEICKER. Dr. Lipsett, thank you very much.

There will be other questions for response to the record, and we appreciate your testimony.

Dr. LIPSETT. Thank you.

[The information follows:]

Statement of Dr. Mortimer B. Lipsett

The research of the National Institute of Child Health and Human Development encompasses the life-span from conception through pregnancy, birth and infancy, and into childhood, adolescence and the critical years of reproduction. Because of its scope, the Institute's mission touches the life of every man, woman, and child in the United States.

Each step of the life cycle presents exciting research challenges and opportunities.

Conception

One of every 10 U.S. couples is troubled by infertility -- the inability to conceive or bear children. As a result of medical research, however, the outlook for these couples has improved considerably over the past 5 to 10 years. NICHD-supported scientists won a Nobel Prize in 1977 for discovering the hormone produced in the brain that regulates reproductive hormones in both men and women. As a result synthetic, modified copies (analogs) of this hormone, which is called luteinizing hormone-releasing hormone (LHRH), have been developed to treat successfully certain causes of infertility in both men and women. We have found that LHRH must be given intermittently at specific time intervals to mimic the natural secretory pattern. This has enabled physicians to induce a single ovulation rather than the multiple ovulations that often occurred with previously used fertility drugs, thereby making the pregnancy safer for mother and infant. Thus, basic research has been taken from the laboratory to the clinic.

Pregnancy and Fetal Development

The events of pregnancy, fetal development, and birth present the greatest opportunities in medicine for the prevention of some of the most costly and devastating problems of our society. The two leading causes of infant death in the U.S. are premature births and birth defects. Many lifelong physical or mental disabilities, including mental retardation, originate in the fetal period.

To combat these problems, the NICHD supports and conducts an intensive research program on the normal physiology of pregnancy and fetal development in order to understand better where, when, and how problems develop.

Low birth weight (intrauterine growth retardation) is a major cause of infant mortality and morbidity. NICHD-grantees have now developed an animal model for intrauterine growth retardation. Knowing that fetuses ingest amniotic fluid, researchers added specific nutrients to this fluid in pregnant sheep and reversed experimental fetal growth retardation. This research may ultimately lead to antenatal nutritional therapy in humans.

This research is part of a larger research program on nutrition during pregnancy. The mother's life style, including smoking and drinking and substance abuse, greatly influences the development of the infant. NICHD-supported investigators have confirmed the deleterious effects of smoking on fetal development, and it was NICHD-supported scientists who identified the fetal alcohol syndrome in

infants born to alcoholic mothers. NICHD intramural scientists have shown in monkeys that alcohol in the mother's blood stream causes a decrease in blood flow to the fetus, resulting in temporary but substantial oxygen deprivation. This may be one of the mechanisms responsible for the mental retardation associated with fetal alcohol syndrome.

Other nutritional effects may be more subtle. One group of NICHD-supported investigators, using a rat model, found that when rats were placed on a minimally deficient protein diet during pregnancy, the litter size, the weight of the infant rats (pups), and the weights of the pups' brains were identical to rat pups fed a standard protein diet. However, irreversible changes in behavior and brain structure attested to the severe lasting effects of inadequate diet during pregnancy. These data have obvious implications for the nutrition of pregnant women.

The method of birth itself has been found to influence later parent-child interactions. One out of every five births in the U.S. is now by cesarean section. NICHD scientists are studying the psychological consequences of cesarean childbirth for the mother, father and infant. Parents whose infant was born by cesarean appear to act somewhat differently toward their infant than parents whose baby was born normally. The preliminary results of this research have been sufficiently important that the findings have been incorporated into childbirth preparation programs.

Sometimes no matter how careful an expectant mother has been about her diet, her smoking, drinking, and other health habits, something goes wrong during fetal development and her baby is born with a birth defect. The defect can be obvious such as the absence of an arm or leg or it can be less apparent but even more devastating such as a lethal inborn error of metabolism or mental retardation.

NICHD scientists are attacking birth defects on two fronts: first, they are working to develop treatment techniques, but perhaps more important in the long run, work is going on to prevent the occurrence of these defects.

In the experimental animal, molecular geneticists are learning how genes program the development of large structures such as limbs. In experiments with monkeys, NICHD scientists are developing therapies to treat fetal defects before birth.

These include direct administration of medicines to the fetus, tissue transplants, and <u>in utero</u> surgical repair of certain anatomical defects. The work with animal models must proceed rapidly since fetal therapy is now entering the practice of medicine.

Other NICHD research is aimed at understanding the most basic elements of fetal brain development. It is now possible to follow the movement of nerve cells as they form communication circuits. Errors in brain development, which can be caused by genetic, nutritional and other factors, are responsible for most cases of mental retardation.

<u>Infancy</u>

A premature or low birth weight infant born in the U.S. has a better chance of surviving than it would any place else in the world.

In part this is due to NICHD-supported basic and applied research which clarified the nutritional and environmental needs of these infants. For example, we have found that there are constituents of human breast milk that hasten maturation of the immature digestive system and protect infants from infections.

The Institute's research mission includes the social, behavioral, and emotional as well as the physical development of infants. We have now shown that babies are much more aware and responsive to their environments than was previously thought. Even at six months of age a baby can distinguish between vowels and consonants, and an infant as young as a day old can tell its mother's voice from others. These and other data have produced a complete shift in our thinking about an infant's capacity to comprehend and learn.

NICHD scientists have applied computer technology to measure infants' reactions to visual and auditory stimuli. These measurements can detect disorders of sensory processing and brain function in very young infants. Early identification of these problems is important so that appropriate interventions can be started as soon as possible.

Childhood

Some developmental problems are not apparent until the child has left infancy. About two million children in the U.S. fall below the third percentile in height. NICHD-supported scientists discovered the structure of growth hormone releasing factor (GRF), a hormone produced in the brain which regulates the production of growth hormone. This enables us to understand how the brain controls growth in animals and humans and to explain how psychosocial deprivation can stunt growth in children. In addition to its usefulness in treating growth disorders, GRF has other important potential uses in treating diabetes, wound healing, and burn therapy.

In a major advance in genetic engineering, NICHD-supported scientists have transferred a gene for growth hormone from rats to mice, resulting in mice that grew to twice the normal weight. This is the first time a gene from one species has been successfully transferred into another species and "worked" in the host species the way it is supposed to "work" in the donor. This is the opening sentence in a new chapter of molecular biology that will teach us how genes turn on, or "express" themselves. Therein lies a new approach for future treatment of both genetic diseases and cancer.

In cystinosis, a rare disorder that may be a model for some other genetic diseases, NICHD scientists have shown that the problem lies with inefficient transport of toxic substances out of the cell. In other studies, we have developed new ways of predicting the interaction of humans with their environment by defining their genetic susceptibility to toxins.

An exciting advance on the behavioral side of pediatric medicine is the development of computer-assisted learning programs for retarded children who have difficulty in using written and oral information. Recently, behavioral scientists have broken the learning process into separate subprocesses such as the encoding of information and the use of different memory processes. Advances in computer technology make it possible to teach retarded children to master

these component processes so that they can learn to read and apply new information more effectively.

Adolescence

Many of the problems of adolescence are behavioral and social rather than medical. In this age group, accidents are the leading cause of death. NICHD-supported scientists are describing the factors that result in adolescents' propensity for risk-taking behavior, and the acquisition of health habits. The motivations behind the initiation of smoking, and the elements influencing adolescents' decisions about sexual behavior are areas of research interest to the NICHD.

Adulthood

Early adulthood is the period of life when both men and women are making decisions about marriage, contraception, and childbearing.

NICHD researchers have shown that oral contraceptives have a protective effect against endometrial and ovarian cancer and do not increase the occurrence of breast cancer. We have previously reported that the oral contraceptive has minimal risks for young, healthy women; however, we also noted that for women over the age of 35, particularly women who smoke, oral contraceptives significantly increase the risk of heart attack and stroke. It is information such as this that helps individuals make decisions about contraceptive choices.

In other contraceptive development research, scientists are taking advantage of the finding that LHRH can induce ovulation safely and yet, in a different mode of administration, block ovulation and sperm production. Clinical trials, using LHRH analogs as contraceptive agents, are now underway in both men and women.

Reproductive health is very important at this point of the life cycle. LHRH analogs are being tested in clinical trials as a treatment for endometriosis, a source of great discomfort for many women and a major cause of infertility. LHRH analogs are also being tested as a possible treatment for polycystic ovarian disease. And in men, LHRH has been shown effective in restoring fertility to some men who were rendered sterile by medical treatments such as chemotherapy treatment for cancer.

Increased understanding of the factors underlying changes in the fertility of individuals and of society is an important part of the NICHD research program. NICHD research has found that a major emerging pattern in our society is the delay of childbearing and a marked increase of first births to women over the age of 30. Delayed childbearing may carry with it a mix of social and economic benefits and increased medical risks. The decision to delay a first birth is related to the decision to delay marriage -- a growing phenomenon. This has implications for contraceptive practices and overall fertility rates.

Thus, at each point in the life cycle, NICHD research in the biomedical and behavioral sciences is designed to improve the health and well-being of infants, children, adolescents and adults.

Budget Request

Mr. Chairman, the National Institute of Child Health and Human Development requests $256,592,000 for fiscal year 1984, an increase of $2,937,000 over the 1983 level. I will be pleased to answer any questions you may have.

Biography of Dr. Mortimer B. Lipsett

Name: Mortimer Broadwin Lipsett

Present Address: 5204 West Cedar Lane, Bethesda, Maryland - 20814

Birth: February 20, 1921, New York, N. Y.

Marital Status: Married - Two Children

Education:

1943 - A.B., University of California
1947 - M.S., University of Southern California
1951 - M.D., University of Southern California
Certified: American Board of Internal Medicine, 1958
Recertified: 1974 and 1980

Professional History:

1946	Research Assistant, University of Southern California
1947	Research Associate, University of Southern California
1951-1952	Intern, Los Angeles County Hospital
1952-1954	Resident, Internal Medicine, Sawtelle Hospital, Veterans Administration, Los Angeles, California
1953-1954	Research Assistant, Cardiology, University of California
1954-1956	USPHS Fellow, Sloan-Kettering Institute, New York
1956-1957	Assistant Member, Sloan-Kettering Institute, New York
1956-1957	Assistant Attending Physician, Memorial Center, New York
1956-1957	Instructor in Medicine, Cornell University Medical College, New York
1957-1959	Medical Officer, Endocrinology Branch, National Cancer Institute, National Institutes of Health, Bethesda, MD
1957-1960	Instructor in Medicine, Howard University School of Medicine, Washington, D.C.
1959-1966	Assistant Chief, Endocrinology Branch, National Cancer Institute, NIH, Bethesda, MD
1960-	Associate Clinical Professor in Medicine, Howard University School of Medicine, Washington, D.C.
1960-1961	Visiting Scientist, Karolinska Hospital, Stockholm, Sweden
1963-1965	Head, Endocrinology Service, Endocrinology Branch, National Cancer Institute, NIH, Bethesda, MD
1966-1970	Chief, Endocrinology Branch, National Cancer Institute, NIH, Bethesda, MD

1970-1974 Associate Scientific Director (RB), Intramural Research, National Institute of Child Health & Human Development, NIH
1970-1974 Chief, Reproduction Research Branch, NICHD, NIH
1974-1976 Director, The Cancer Center Inc. for Northeast Ohio, Cleveland, Ohio
1974-1976 Professor of Medicine, Case Western Reserve University School of Medicine, Cleveland, Ohio
1978- Clinical Professor, Department of Medicine, Uniformed Services University of the Health Sciences, Dept. of Defense, Bethesda, MD
1976-1982 Director, Clinical Center, National Institutes of Health, Bethesda, MD
1976-1982 Associate Director for Clinical Care, NIH, Bethesda, MD
1982-Present Director, National Institute of Child Health and Human Development

Professional Organizations:

American Association for the Advancement of Science
American Association for Cancer Research
American Federation for Clinical Research
American Physicians Fellowship, Inc., Board of Trustees - 1979
American Society for Andrology, Council - 1982
American Society for Clinical Investigation
Association of American Physicians
The Endocrine Society
  Chairman, Postgraduate Committee, 1973-1974
  Secretary-Treasurer, 1974-1978
  President, 1979
Harvey Society
International Society of Endocrinology
  Secretary General, 1976-
Society for Study of Reproduction

Committees and Boards:

1958-1960 Member, Clinical Research Fellowship Review Panel, National Institutes of Health, Bethesda, MD
1962-1965 Co-Chairman, Clinical Research Committee, NIH, Bethesda, MD
1963-1964 Chairman, Endocrinology Committee, National Cancer Institute, NIH, Bethesda, MD
1963-1965 Member, National Institutes of Health Committee on Diagnosis and Treatment
1963-1966 Member, Specialty Fellowship Board of the National Cancer Institute, NIH, Bethesda, MD
1963-1967 Member, Committee on Therapy, American Cancer Society
1964-1977 Editor, Steroids
1966-1968 Member, Editorial Board, Journal of Clinical Endocrinology and Metabolism
1966-1970 Chairman, National Cancer Institute Breast Cancer Task Force

1967-1970 Member, Scientific Directorate, National Cancer Institute, NIH
1968-1972 Member, Reproductive Biology Study Section

1968-1973	Editor-in-Chief, Journal of Clinical Endocrinology and Metabolism
1969-1976	Member, American Board of Internal Medicine, Endocrinology Test Committee
1970-1973	American Cancer Society, Advisory Committee on Biochemical and Chemical Carcinogenesis
1972-1974	Chairman, Education Committee, NIH
1972-1974	Member, Technical Review Committee, Reproductive Biology, World Health Organization
1973-1976	Member, Veterans Administration Endocrinology & Metabolism Review Board
1974-1976	Member, Program Organizing Committee, Fifth International Congress of Endocrinology
1974-1981	Board of Editors, Cancer Research
1975-	Endocrinology and Metabolism Committee, Food and Drug Administration Member (1975-1977); Chairman (1978-1980); Consultant (1980-)
1979-	Member, Organizing Committee, International Steroid Congress
1980-	Member, International Advisory Board, Technion-Israel Institute of Technology
1981-	Member, Editorial Board, IRB

Honors and Awards:

1950	Alpha Omega Alpha
1955	Alfred P. Sloan Award for Cancer Research
1959	Diplomate, American Board of Internal Medicine
1962	Fellow, American College of Physicians
1969	Superior Service Honor Award, Department of Health, Education, and Welfare
1973	Corresponding Member, German Endocrine Society
1976	Distinguished Leadership Award of the Endocrine Society
1980	Senior Executive Performance Award
1981	DHHS Distinguished Service Award
1982	Senior Executive Service Meritorious Rank Award

Listed In:

Who's Who in America
World Who's Who in Science
American Men and Women of Science

Questions Submitted by the Subcommittee

ADOLESCENT FERTILITY

Question: Your Institute conducts research on adolescent pregnancy, the likelihood that adolescent sexual behavior can be modified, and on theories for preventing unintended pregnancies among adolescents. To what extent is your research in these areas duplicated by the Adolescent Family Life Program (AFLP)?

Answer: The programs in the National Institute of Child Health and Human Development (NICHD) and AFLP are complementary rather than

duplicative. Adolescent fertility-related behavior is quite complex and requires a variety of approaches. The NICHD program emphasizes basic research in human behavior and risk-taking and covers a very broad range of concerns relating to the causes, correlates, and consequences of adolescent fertility-related behavior. The AFLP research program is part of a larger program which includes health services, demonstration projects, and operations research, and which emphasizes substantive issues of special interest such as family involvement.

Question: Do representatives of the Adolescent Family Life Program ever consult you to determine whether you have covered ground that they plan to get into?

Answer: Yes, there is very close coordination and cooperation between staff of AFLP and the Center for Population Research (CPR). AFLP representatives consult with CPR staff regarding planning of research initiatives, and they attend CPR research workshops as well as meet with CPR program representatives regarding program areas they may develop. CPR has urged AFLP to pursue its interest in adoption, given the lack of research and data on this very important aspect of teenage fertility behavior. As another example, a data archive project currently funded by AFLP builds on a project originally funded by CPR. We knew of AFLP interest in this area and felt it was a very useful project. While not involved in the writing of the Request for Proposals for AFLP, a representative of CPR, Dr. Wendy Baldwin, serves as Chair of the National Advisory Committee for the archive project.

INFANT MORTALITY

Question: We seem to get mixed signals on infant mortality in the U.S. We understand that Japan may have an infant mortality rate of 7 per 1,000 live births. Why can Japan do better than the U.S.?

Answer: Since the early 1950s, several countries in the Far East have had striking decreases in infant mortality to levels that are now more close to those in the U.S. These include Hong Kong, Singapore, and most significantly, Japan. These same groups show very low ratios when they migrate to America. Countries, such as those in Northern Europe, have populations which are culturally more uniform than our own. With the rapid economic progress they have experienced since World War II, they have developed a favorable social environment which is supported by a technically competent health care system. The results have been dramatic improvements in health, including the infant mortality rate.

It is well known that the cultural diversity in the United States includes economically and socially disadvantaged sub-groups which contribute disproportionately to infant mortality. Beyond that, there are more high risk pregnancies in the U.S. than in Japan. For instance, in a comparative study 5.5% of births in six states were to women with four or more previous children vs. 0.3% in Japan; and 5.7% of the U.S. births were to mothers under age 18 vs. 0.1% in Japan.

It should be emphasized that the U.S. has been making excellent progress on infant mortality, which continues to decline and fell an additional 6% from 1980 to 1981. Many of the technological

advances that have contributed to improved infant survival throughout the free world have been pioneered in the United States. Partly as as a result of these techniques, at each weight level, infant mortality in the United States is as good or better than any country in the world. Our problem is the excess of very low birth weight infants who have high mortality. We expect further improvement from continuing research. However, the better infant mortality rates achieved with existing technology in Sweden and other countries suggest that social and medical care delivery problems also need to be addressed.

Question: There has been concern expressed that in the current high unemployment pregnant women aren't getting the health care they need and infant mortality may be rising as a result. However, we are told by the Public Health Service that last year infant mortality was 11.2 per 1,000 live births -- very low for this country. What is the truth of the matter?

Answer: Registration of births and deaths is a State function. Data collected by States are forwarded to the National Center for Health Statistics (NCHS) which then compiles national vital statistics. NCHS has recently investigated concerns regarding U.S. infant mortality trends and high unemployment. In summary, they find that the latest national data on prenatal care indicates that the percentage of woman seeking prenatal care early in their pregnancy has been increasing and that present infant mortality data are insufficient to support the contention that there has indeed been an upturn in the infant mortality trends. Recent data on U.S. infant mortality indicate that the decline in infant mortality, evident since the mid 1960s, has been sustained. Annual changes in infant mortality rates by State continue to show an overall downward trend. There are, however, yearly fluctuations in the number of births and deaths. While some local jurisdictions may be experiencing real increases in infant mortality rates or in the number of women coming to childbirth without prenatal care, the many factors contributing directly and indirectly to infant ill health and poor survival make it difficult to detect changes in trends. NICHD continues to explore opportunities to improve maternal and infant health through basic and applied research. Our approaches include emphasis on prevention as well as on highly specialized treatment.

CONTRACEPTIVE RESEARCH

Question: One of your major functions is to evaluate the safety of various birth control methods. We understand you have been examining "LHRH," a brain hormone which you say appears to have promise as a contraceptive agent in both women and men. What have you found -- and how close are you to forming any conclusions about this hormone?

Answer: Our program has been involved for some time with the synthesis of modified copies (analogs) of LHRH which are much more potent and longer acting than the natural hormone. We are conducting clinical studies in both men and women volunteers utilizing different analogs. In women, investigators have been able to block ovulation by utilizing several methods and timing sequences of administering the drug. Daily administration of these drugs provides for good contraception; however, it is frequently accompanied by irregular bleeding or by the absence of menstrual periods. Therefore, we need

to discover how to maintain a regular menstrual pattern during the use of LHRH.

In men, production of spermatozoa can be partially blocked by the administration of LHRH analogs. A new method of administering these drugs on a continuous basis has been tried in non-human primates and has rendered them temporarily infertile. We have made plans to test this approach in men.

All of the studies cited above whether in men or women have been conducted with a class of analogs called "agonists." Another class of LHRH analogs, the so-called "antagonists," are now becoming available for clinical studies. While "agonists" mimic the action of the natural hormone, "antagonists" block its activity. In animals, especially males, the antagonists have a somewhat different spectrum of activity and thus may provide another clinically effective approach to fertility regulation. It is our opinion that several years of clinical studies are required before we will be able to reach any definitive conclusion on the potential that these drugs offer for practical fertility regulation.

Question: What clinical trials are you conducting on contraceptives -- and how much will you spend on this in fiscal 1984?

Answer: We are evaluating the potential of LHRH analogs as fertility regulating agents for both men and women; assessing the effectiveness and safety of cervical caps and of a long-acting injectable contraceptive; conducting studies on improved design of cervical caps; and evaluating a new oral contraceptive. We have plans to study fertility awareness methods, techniques that are integral to the effectiveness of natural family planning methods. We are projecting that in fiscal 1984 we shall spend approximately $3.5 million in support of ongoing clinical studies.

MENTAL RETARDATION

Question: We know that congenital defects are a major cause of mental retardation in infants. What progress are you making in the mental retardation area?

Answer: NICHD is supporting biomedical and behavioral studies to enhance fundamental knowledge of the basic causes of the over 200 syndromes associated with mental retardation.

Data from one such study indicate that children with certain forms of congenital hypothyroidism who are treated adequately with thyroxin before clinically diagnostic signs and symptoms appear are protected against the neuropsychological impairment when treatment is delayed. At present, newborn screening programs for congenital hypothyroidism are carried out in all 50 states. With the exception of 8 states where newborn screening is done on a voluntary basis, the programs have been legislatively mandated. The screening programs identified 740 children who have congenital hypothyroidism out of the 3,478,000 newborns who were evaluated in 1981. Only 5 percent of the affected children showed clinical signs and symptoms of the disorder shortly after birth. Thus, in the absence of screening programs for hypothyroidism, 95 percent of infants with the condition would have escaped prompt treatment. These data point to the importance of early screening and treatment of infants for

hypothyroidism which is estimated to occur once in 4,700 newborn infants.

Research has established that screening and early dietary treatment of infants born with phenylketonuria can prevent the mental retardation and developmental problems associated with this condition. Other studies have shown that dietary treatment can be discontinued at age 6 years without any major deleterious effects; however, children who continue on a phenylalanine restricted diet past 6 years of age appear to show better development. The early screening and treatment programs for phenylketonuria established in the 1960s have dramatically reduced the frequency of mental retardation associated with this problem. As a result, young women with treated phenylketonuria have matured and are approaching their child bearing years as essentially normal persons with reproductive capacity. Studies have shown that the fetuses of these phenylketonuric women are particularly vulnerable in utero to high maternal phenylalanine blood levels. The NICHD currently supports and is proposing new studies aimed at establishing the appropriate dietary management for prospective and pregnant women with phenylketonuria in order to prevent mental retardation and other associated defects in their children.

PREMATURITY

Question: There is some suspicion that infection may play a role triggering premature labor. What can you tell us about this?

Answer: Some investigators have reported finding that genitourinary tract infections (GTI) during pregnancy have an adverse effect on infant birth weight and survival. It has been proposed that GTI may in some instances give rise to a stimulus to preterm labor. This would account for the higher incidence of low birth weight infants born to mothers with GTI as reported in some studies. Several explanations for the apparent relationship between GTI and the decrease in birth weight can be offered -- direct spread of the infection to the fetus and/or placenta could produce growth retardation; the infection could cause an inflammatory process of fetal membranes and lead to early rupture; or damage to placental tissue caused by bacteria could lead to low oxygen levels in the fetus and poor development. The results of studies that suggest a potential effect on labor are consistent with the biochemical events known to be associated with the timely initiation of labor at term. According to current concepts, normal labor begins with the activation of an enzyme which stimulates uterine contractions and labor. It has been postulated that bacteria in the maternal genitourinary tract may provide an external source of the enzyme that is capable of prematurely initiating the biochemical sequence that leads to labor. In order to obtain an answer to this most important question, the NICHD, in collaboration with the National Institute of Allergy and Infectious Diseases (NIAID), is carrying out a multicenter clinical trial to determine whether treatment of infections due to specific bacteria reduces the incidence of prematurity.

HIGH RISK PREGNANCIES

Question: I think we all are aware of the dangers to the infant in a pregnancy where the mother has diabetes. The incidence of congenital defects in such infants can be great. What research are you doing in this area -- and with what results?

Answer: The NICHD-Diabetes In Early Pregnancy Project is studying the problem of congenital malformations in infants of diabetic mothers. Women are being recruited prior to pregnancy so that information can be collected during the first two months of pregnancy, the period during which the fetal organs develop. These women are being treated as intensively as possible to normalize their blood sugars in an effort to determine whether this approach will reduce the frequency of congenital malformations.

Following women from the very beginning of pregnancy will also enable us to gather information on fetal loss rates in both the diabetic and control populations. We will be able to determine whether the diabetic woman is at increased risk of suffering a fetal loss. Recruiting women prior to pregnancy is an innovative approach, and locating enough subjects has been a challenge. At current pregnancy rates, we estimate that the last pregnancies will be completed in June 1985.

Question: To what extent do you consult with the Arthritis/Diabetes Institute in your research -- particularly, with regard to your work on a micro-electronic insulin pump?

Answer: The staffs of the NICHD and the NIADDK communicate frequently regarding their respective interests and responsibilities in the area of diabetes research. Both Institutes support research programs aimed at developing physiologic insulin delivery systems. The NICHD is particularly interested in supporting research on miniaturized insulin delivery systems for use in childhood. The goals and accomplishments of the NICHD diabetes research program are formally discussed with NIADDK staff eight times per year at meetings of the HHS Diabetes Mellitus Interagency Coordinating Committee, and at meetings of the NIH Diabetes Mellitus Coordinating Committee. In addition to these formal contacts, members of the two Institutes often meet informally to discuss research advances.

Question: What new research is underway to deal with the problems stemming from low birth weight among infants -- including metabolic and respiratory problems?

Answer: New research is included in the following areas:

Nutrient Requirements -- The survival of low-birth-weight infants poses great nutritional challenges. Protein and energy requirements for maintenance of acceptable rates of growth and development after pre-term or low birth weight birth must be ascertained, as well as requirements for vitamins, minerals, and trace elements. Research supported by the NICHD has made it clear that differing rates of growth can be obtained by adjusting the caloric and nitrogen density of the diet. Currently, several studies are devoted to this issue because the physician must eventually decide how to substitute for the complex nutrient functions of the placenta for an extended period of time. These investigators are doing research on the following issues: total parenteral nutrition (intravenous), enteral nutrition (fed directly into the intestine either through a nasal tube or a tube directly into the intestine), metabolic balances and calorie requirements for growth and metabolic needs, research on immunologic and nutrient composition of colostrum and human milk collected from mothers who deliver at various gestational ages.

Biochemical Immaturity -- Appropriate nutritional therapy for the prematures must also consider the immaturity of the intestinal tract and of the systems that produce the enzymes necessary for digestion and nutrient absorption to occur. It has been found that saturation of these systems is attained at nutrient concentrations that vary directly with gestational age. Furthermore, infants born prematurely have requirements for specific amino acids that are deferred from those essential to infants born at term. In managing the nutritional therapy of premature infants, the medical team must aim to support high rates of physical growth and to maintain normal metabolic processes.

Human Milk Banking -- The NICHD is supporting research on human milk banking to develop techniques for collecting, fractionating, storing, and distributing human milk for use in clinical situations. Workable methods of collection, refrigeration, and storage that preserve viable populations of immunologically active cells in human milk colostrum, and methods to destroy the bacterial and viral contaminants while at the same time leaving intact biologically active properties of milk are being developed.

Development of Digestive Function in the Newborn -- The normal newborn possesses a limited reserve of energy stored in the form of body fat. At birth, the premature infant has less fat and an incompletely developed intestinal tract that must quickly adapt to support all of the infant's energy and growth needs. Several studies are underway to characterize the progression of digestive processes that become functional near the time of birth and thereafter.

Pulmonary Function -- One of the most dramatic changes at birth is the initiation of respiratory function. Scientists have recently observed that the fetus experiences breathing movements before birth, and are studying the control of respiration before and after birth. These studies are important for an understanding of the Sudden Infant Death Syndrome and Respiratory Distress Syndrome.

Endocrine Function -- Data suggesting that the normal fetus may not have normal thyroid function until late in gestation, coupled with observations that fetal thyroid deficiency has minimal effects on fetal growth and development, have led to reevaluation of concepts of fetal thyroid hormone dependency. Studies are turning to questions concerning the thyroid hormone levels appropriate for the increasing number of very small premature infants receiving care, the role of thyroid hormone in neonatal heat production, and the maturation of tissue hormone receptor systems.

SUDDEN INFANT DEATH SYNDROME

Question: Sudden Infant Death continues to be a major concern. You have done a lot of research in this sensitive area, but are we any closer to a solution?

Answer: Numerous studies have been supported by NICHD which address the many hypotheses advanced to explain SIDS. Scientists agree that multiple causes are involved and that several fundamentally different mechanisms can result in sudden and unexplained infant death. Therefore, the progress toward a solution to this problem is by its very nature a slow process. Knowledge accumulated through intensive research has clarified some aspects in the physi-

ology of development, specifically regarding sleep, cardiorespiratory and metabolic functions, and immune responses to infections. Dysfunctions in the central nervous system are under scrutiny, and studies in this area are promising to amplify our understanding of SIDS. The large NICHD Cooperative Epidemiologic Study of Risk Factors over a period of years has confirmed that SIDS is more frequent in male than in female infants, among low-birth-weight infants or prematures, and in babies whose mothers had inadequate prenatal care or who smoked during pregnancy. The study also supports the view that DPT immunization does not cause SIDS.

Question: What is the significance of the higher levels of T-3, a thyroid hormone, found in SIDS victims?

Answer: The past studies supported by NICHD indicated that T_3 levels were elevated postmortem in infants dying of SIDS. In subsequent studies, no differences were found in neonatal T_3 and T_4 values between infants who later became SIDS victims and those who survived. These determinations were done on specimens collected in a screening program for congenital hypothyroidism.

FETAL MEDICINE/GROWTH RESEARCH

Question: We understand that you are recording some striking advances in fetal medicine. Bring us up to date on your general progress. For example, what are you doing on immature lung development in the fetus?

Answer: Fetal medicine is advancing on two fronts. One, most important is that of detection of abnormalities in utero or prenatal diagnosis, and the other addresses specific interventions or treatments to be carried out before birth. Once diagnosed, several fetal enzyme deficiencies and metabolic derangements have been treated or are potentially treatable by providing the missing nutrient, vitamin, or hormone, or by dietary manipulation to prevent accumulation of a damaging metabolite. Although numerous anatomic malformations are detectable before birth, the only ones at present that warrant consideration for treatment in utero are simple structural defects that interfere with organ development and whose alleviation might allow fetal development to proceed normally. Current studies in animal models are helping to define the functional changes that accompany some lesions, but more work is needed.

Tests have been developed to measure fetal biochemical and physiological maturity. A major risk involved in delivery before full maturity is that the infant will develop respiratory distress syndrome. New and improved tests have been developed to determine lung maturation and to help in timing the delivery of that fetus. Important research is being supported on the qualitative changes after birth in surfactant (the substance that keeps the air sacs in the lung form collapsing; surfactant permits normal respiratory exchanges and function). The NICHD is currently supporting studies designed to examine the biochemical basis and mechanisms for maturation, stabilization and regulation of surfactant function in the developing fetus and newborn. Artificial surfactant and surfactant isolated from human amniotic fluid have been administered to infants with respiratory distress syndrome with good results. Studies to refine this new therapeutic approach are continuing.

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Question: Of the more than 3 million babies born in the U.S. each year, 100,000 grow up shorter than they should. Tell us what progress you're making with the use of synthetic growth hormone.

Answer: NICHD investigators are participating in two clinical studies using synthetic growth hormone. The first study involves children who are unable to make their own growth hormone. The second involves children who apparently make an abnormal growth hormone that is biologically inactive. As further data are obtained concerning the safety and efficacy of synthetic growth hormone, we envision that studies will be started to learn whether we can treat still other causes of short stature with synthetic growth hormone. NICHD researchers hope that the commercial production of synthetic growth hormone will increase the supply and decrease the cost of this hormone so that all children who would benefit from it can receive it.

Question: Your justification reports on an experiment in which you transferred a gene for growth hormone from rats to mice -- and grew mice to twice their normal weight. To what extent do you view gene transfer as a future method for correcting inherited genetic disorders?

Answer: We are not now contemplating an attempt at gene transfer as cure for any human genetic disorder since the methods are currently far too experimental for such an approach. However, the introduction of isolated genes into mouse embryos with the observation of their activity in the adult mouse, is a highly promising procedure for several reasons. First, the method will allow detailed studies on the action of genes during development and on the structural requirements for normal gene function. This approach should lead to substantial progress in understanding normal development as well as the cause for certain genetic diseases. Second, the method may allow the production of animal models of human genetic diseases for which no good models are currently available. Such models would be of great importance in efforts to understand these conditions and find suitable treatments. Third, the method may prove valuable in live-stock genetics in introducing desired traits into commercially important animals. And finally there is hope for correction of several human genetic deficiency.

Question Submitted by Senator William Proxmire

DIRECT OPERATIONS

Question: You indicate under direct operations that you are budgeting an additional $25,000 for the Consumer Information Center. Could you explain this increase as well as your total $68,000 Consumer Information Center budget to the Committee.

Answer: This expense is a GSA tap which helps support distribution of consumer information literature developed by the various agencies of the Federal government. It is my understanding that GSA taps all Federal agencies on a pro-rated basis. The increased support proposed in the NICHD FY 1984 budget for the Consumer Information Center represents a mandatory increase.

NATIONAL EYE INSTITUTE

STATEMENT OF DR. CARL KUPFER, DIRECTOR

ACCOMPANIED BY:

DR. JAMES B. WYNGAARDEN, DIRECTOR, NIH
EDWARD H. McMANUS, DEPUTY DIRECTOR, NEI
H. RICHARD MILLER, ASSISTANT DIRECTOR, BUDGET, DIVISION OF FINANCIAL MANAGEMENT, NIH
ANTHONY ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET, DHHS

BUDGET REQUEST

Senator WEICKER. Next, we will hear from the National Eye Institute, which is one of the fastest growing branches of NIH.

In fiscal year 1982, it received an appropriation of $127 million, but the revised NIH budget for fiscal year 1984 is $142 million. This is slightly above the 1983 level.

The chief witness of the Eye Institute is well known to this subcommittee, Dr. Carl Kupfer, the Director, who will testify in behalf of the Institute's budget.

Dr. Kupfer, please proceed.

Dr. KUPFER. Thank you, Mr. Chairman.

Let me just introduce Mr. Edward McManus, the Deputy Director of the National Eye Institute on my left.

Each year, about 50,000 people in this country become blind. And nearly 1 million suffer serious visual impairment. This costs our Nation $14 million annually.

In human terms, the costs of visual loss are so great that public opinion polls have shown we Americans fear blindness more than any other disorder except cancer.

In recent years, research advances fostered by the National Eye Institute have done much to alleviate these concerns, yielding great benefits in terms of blindness, prevention, and savings to society. For example, last May we announced the results from a nationwide clinical trial which show that laser treatment can save the vision of some people who have aging-related maculopathy. This eye disease, which is also called senile macular degeneration, is a leading cause of blindness among the elderly.

It has been estimated that appropriate use of this laser treatment could prevent blindness in 13,000 Americans each year and save $57 million annually. That is the amount that would have to be spent to support and care for them if they were to lose their vision.

It is the National Eye Institute's responsibility to make sure that investments in vision research for clinical studies such as this one, and for

basic research as well, continue to yield high dividends both in human and economic terms.

To attain this objective, it is necessary to set priorities. At the National Eye Institute, research priorities are established with the aid of our unique planning process. We collaborate with the National Advisory Eye Council and panels of expert consultants in a periodically updated study of vision research, taking stock of recent advances and identifying areas where there is the greatest need and opportunity for new research.

The results of this study are incorporated into a detailed report, a management tool that is used by the National Eye Institute staff, the National Advisory Eye Council, and vision researchers as well.

This plan serves as a stimulus to research in areas identified as high priority, helping to foster the new advances needed to lower the national toll of eye disease and visual disability.

This constitutes my opening statement summary. And perhaps I can move to the questions that you have asked the other Institute Directors.

Ever since 1972, the National Eye Institute has identified investigator-initiated research as its highest priority. At the present time, approximately 93 percent of our extramural budget supports individual investigator-supported research grants. Therefore, we feel that the shift of funds into investigator-initiated research is very important.

We have approached this problem by reducing the funding of noncompeting grants approximately 10 percent and reducing the average cost of competing grants approximately 17 percent. This enables us to maintain momentum in the visual research community because we are continuing to support new investigators.

There are two clinical trials that we will perhaps put off until the next fiscal year. One would deal with improvement in the diagnosis of strabismus to determine what operation would be the best approach to correcting this condition of cross-eye or walleye in children.

The other trial would be a pilot project in the treatment of retinitis pigmentosa, which is a hereditary degeneration of the retina that occurs in children and young adults and is a major cause of blindness in the younger population.

Concerning the roller-coaster effect, this was a major motivation for beginning NEI program planning back in the mid-1970's. We believe that such fluctuation is a very great deterrent, not only to attracting new investigators, but to maintaining NEI's credibility with the research community by being able to say, "We can give you some continuity in support of your research effort."

Therefore, through program planning and by identifying high-priority areas, we have tried to protect certain areas that the research community and our National Advisory Eye Council have identified as the highest of priorities. In all our negotiations, we look not only at the individual project, but the program priority of the work that is being proposed.

In certain areas, we have prevented the roller-coaster effect of inconsistent funding by protecting grants in high-priority areas. In general, though, I think the roller-coaster effect is something that we must be very concerned with because most research is long term, a matter of 10 or even 15 years, rather than 2 or 3.

As far as competing grants are concerned, we have increased the number from 229 to 266 grants. This is an increase of 37 grants and approximately $2.979 million.

PREVENTING CATARACT DEVELOPMENT

Senator WEICKER. Your justification makes the point those who have been treated surgically for eye cataracts "would have preferred to have avoided * * * surgery altogether."

And undoubtedly, a lot of these people are elderly.

What progress are you making toward preventing or slowing cataract development, or for treating it nonsurgically?

Dr. KUPFER. There are two major groups in the population who develop cataract. There are the elderly and those with diabetes. Concerning the latter, we know now that aging-related cataract occurs on the average 13 years earlier in the diabetic than in the nondiabetic.

I think we have made some very impressive strides in the development of cataract in the diabetic patient. Clinical trials are about to begin to determine whether we can at least slow the development of aging-related cataracts in the diabetic population. These efforts are specifically aimed at attacking the aspect of cataract development that is related to the diabetes. We actually have drugs that can be used topically to try to effect this change.

Of course, the vast majority of the aging-related cataract population is not diabetic, but progress is being made in trying to find a nonsurgical treatment for these cases as well. We now know at least one mechanism by which the lens, which is ordinarily completely transparent, becomes translucent and then opaque. We can simulate this process in the test tube, but how to translate that information into a treatment for patients still eludes us at the present time.

However, I think that we are moving in the right direction. And we are aware of the fact that if we could just slow the development of aging-related cataract by 10 years, we could reduce by some 45 percent the number of people who would need cataract surgery.

PROGRAM PLANNING PRIORITIES

Senator WEICKER. We understand the new national vision research plan will soon be published and will be the guide for development of your program over the next 5 years.

What priorities will the new plan set?

Dr. KUPFER. The new plan sets priorities in each of the five areas that we are concerned about. In the area of retina, a high priority is being given to the development of a clinical trial to prevent the development of diabetic retinopathy. This is a major cause of new adult blindness in the United States and Western World.

We are also very much concerned with an inflammatory condition of the inner eye called uveitis. For the first time, we have a therapeutic approach to this problem; this will be another high priority.

We want to review and expand our immunological approach to retinal disease. Therefore, there would be a major expansion in immunology research.

We are concerned with retinal degenerations. We have made marked progress in one group of retinal degenerations, gyrate atrophy, in which not only has it been possible to identify the underlying enzyme defect, but also to develop a treatment which has been shown to be successful. This condition affects only a few people, but progress against it gives us an important lead in the prevention of retinal degenerations and retinitis pigmentosa.

In the area of corneal disease, we, too, are very concerned about herpes simplex infection. Although corneal diseases account for only a small amount of blindness, perhaps 5 percent, it is a significant cause of visual disability and frequently is quite painful. Each of us at one time or another has had a foreign body in our eye; we know how uncomfortable that can be.

So we are expanding our development of new drugs for the treatment of herpes infection of the cornea. And we are also going to support a clinical trial to determine if the use of human interferon can prevent recurrences of this disease.

We are also very much interested in extending our knowledge of transplantation immunology, because we are doing more and more corneal transplants and in increasingly difficult cases in which the problem of graft immune rejection is greater.

As far as glaucoma is concerned, we are supporting the development and testing of better lasers for more effective treatment of both narrow angle and open angle glaucoma. This is a very high priority, not only from a scientific point of view, but from an economic one as well. Using a laser, we can convert the surgical treatment of glaucoma from an inpatient to an outpatient procedure, taking a matter of minutes. The economic implications of this are clear.

In the general field of neurobiology, perhaps the greatest concentration of scientific activity is in research on the visual system because this is the one system in which the stimulus—light—and the output—eye movements—can be measured very, very accurately. Therefore, much of the basic research on how the brain functions is being conducted in the visual system.

We are particularly interested in the problem of amblyopia, also called lazy eye. There has been quite a bit of information coming from laboratory studies recently that has bearing on the development of amblyopia and strabismus, as well.

Again, we rely very heavily on laboratory as well as clincial data to help us improve the treatment of these conditions.

As I mentioned earlier, we are also very much interested in cataract research. And I think we have increased our efforts considerably in research on aging-related cataract.

So those are some of our high priorities in the new vision research plan.

COLLABORATION BETWEEN INSTITUTES

Senator WEICKER. One last question. You mentioned two different situations—one dealing with diabetes that relates to your work, and herpes relates to it as well. What kind of cooperation is there between the various centers where the disciplines cross here?

Dr. KUPFER. Between the institutes?

Senator WEICKER. Yes.

Dr. KUPFER. Well, we have, as far as diabetes is concerned, very, very close liaison with the National Institute of Diabetes, Digestive, and Kidney Diseases—NIADDK.

We consult with NIADDK on many of their projects, for instance, their clincial trial of strict versus conventional control of diabetes, in which one of the possible end points is the development of diabetic retinopathy. Members of our staff are on the data monitoring committee for that study.

In addition, we are about to begin a clinical trial on a medical intervention to prevent diabetic retinopathy. We have closely coordinated our activity so it does not interfere with any of the clinical trials that are being conducted by NIADDK.

As far as the herpes situation is concerned, it might be interesting from a historical point of view to mention that the first successful drug used to treat any virus infection was one used to treat herpes virus infection of the eye. And this was developed and tested in the early 1960's by an ophthalmologist using a drug that had been thought to have potential for cancer chemotherapy, but had not worked out.

And from that point on, most of the antiherpetic drugs now on the market or under investigation have been first tested in the eye because it is so easy to produce the infection experimentally in the cornea of laboratory animals and then to monitor the response to the drugs. In supporting such efforts we have been in very close communication with the National Institute of Allergy and Infectious Diseases.

Many of our intramural scientists and many of our program planning activities in this area have been heavily dependent on the scientific input from the National Institute of Allergy and Infectious Disease.

PREPARED STATEMENT AND SUBMITTED QUESTIONS

Senator WEICKER. Dr. Kupfer, thank you very much.

There will be other questions for response to the record. Thank you.

Dr. KUPFER. Thank you, sir.

[The information follows:]

STATEMENT OF DR. CARL KUPFER

Each year about 50,000 people in this country go blind, and nearly a million suffer less serious visual impairment. This costs our Nation $14 billion annually. In human terms, the costs of visual loss are so great that public opinion polls have shown we Americans fear blindness more than any other disorder except cancer.

To reduce these costs, the National Eye Institute supports research aimed at improving the prevention, diagnosis, and treatment of blinding eye diseases and other disorders affecting the visual system.

In recent years, research advances fostered by the National Eye Institute have indeed yielded great benefits, both in prevention of blindness and in savings to society. For example, last May we announced the results from a nationwide clinical trial which showed that laser treatment can save the vision of some people who have aging-related maculopathy. This eye disease, which is also called senile macular degeneration, is a leading cause of blindness among the elderly. It has been estimated that appropriate use of this laser treatment could prevent blindness in 13,000 older Americans each year and save $57 million annually. That is the amount that would have to be spent to support and care for them if they were to lose their vision.

Even greater savings are expected to be realized from the results of an earlier clinical trial supported by the National Eye Institute--The Diabetic Retinopathy Study. Members of this committee may recall that this study proved that laser treatment can dramatically reduce the risk of visual loss in people with another sight-threatening eye disease, diabetic retinopathy. According to our most recent estimates, appropriate utilization of the study results could yield a savings of $454 million a year that would otherwise have to be spent to assist newly blind diabetics.

It is the National Eye Institute's responsibility to make sure that investments in vision research for clinical studies such as these continue to yield high dividends, both in human and economic terms. We believe that wise use of research funds is even more important now that at any time in the past, because we are trying to solve enormous public health problems with a restricted supply of money. To meet this challenge, it is necessary to set priorities. In the next few minutes, I am going to describe several research efforts which the National Eye Institute has identified as being particularly worthy of support in coming years. Each of these high-priority areas of research was selected because it addresses a serious medical need and offers an excellent opportunity for scientific progress.

One of the most exciting areas of vision research today is the application of immunological concepts and methods to the management of inflammatory disorders of the eye. The most important of these is uveitis. This disease of the inner eye is a major cause of severe visual impairment in this country.

Recently, investigators at the National Eye Institute used an immunological approach to the development of a highly promising treatment for uveitis. The breakthrough that led to this treatment was the discovery that many cases of uveitis are autoimmune in origin; that is, they arise because the body's immune system has begun to attack normal tissue. This finding led the investigators to ask whether uveitis might be controlled by cyclosporine, a drug used to prevent the immune system form rejecting newly transplanted kidneys. The first small-scale study testing the effectiveness of cyclosporine in patients with autoimmune uveitis has yielded such encouraging results that we are about to begin a larger controlled clinical trial of the drug.

If National Eye Institute-supported research leads to a successful treatment for uveitis, as we hope it will, and if many cases of blindness and severe visual impairment are prevented as a result, the annual savings to society would be an estimated $30 million.

Another high-priority area of investigation is the search for a means to prevent diabetic retinopathy, the leading cause of new cases of blindness among middle-aged Americans. As I mentioned earlier, laser treatment can reduce the risk of blindness for diabetics who have reached relatively advanced stages of this disease, but naturally we would prefer to have a way to prevent the disease from progressing that far. Hope for such a preventive measure now centers on drugs that inhibit the enzyme aldose reductase. Development of these agents, called aldose reductase inhibitors, was pioneered by the National Eye Institute scientists.

In past years' testimony, I explained that aldose reductase inhibitors have the astonishing capability of blocking some of the harmful effects of diabetes. For example, the drugs can prevent the formation of cataracts in diabetic laboratory animals and can partially reverse nerve damage in human diabetics. Now there is evidence that aldose reductase is present in the retina as well as in these other tissues. This finding suggests that aldose reductase inhibitors may be of value in preventing or controlling the retinal abnormalities caused by diabetes. To test this possibility, the National Eye Institute is planning a clinical trial in cooperation with a pharmaceutical company. The patients in the study will be insulin-dependent diabetics who stand a strong chance of developing diabetic retinopathy. If aldose reductase inhibitors prove safe and effective in this trial, the drugs may one day be used to spare millions of people from the eye problems associated with diabetes.

This research is also of great economic importance: If we can delay the onset of blindness by even 1 year in people with diabetic retinopathy, the net savings to society would total $100 million for that year alone.

Aging-related maculopathy is a retinal disease even more common that diabetic retinopathy. It affects the vision of some 7 million Americans over the age of 60; that's 1 out of every 5 people in this age bracket. Fortunately, only a very small portion of these people have the more serious, neovascular from of the disease in which the risk of severe visual loss is greatest. An estimated 14,000 people a

year go blind because of this neovascular type. Thanks to the clinical study I mentioned earlier, we know that laser treatment can help to reduce the risk of going blind for many people with this type of aging-related maculopathy. However, it would be far better if we had a means of preventing or halting this disease altogether, both the neovascular type and the milder form which usually causes a lesser degree of impairment.

Recently, research supported by the National Eye Institute has yielded information that eventually may be used to devise preventive measures for aging-related maculopathy. Laboratory studies suggest that two factors--light and diet--may play a role in determining whether the retina will undergo long-term degenerative changes. The theory being investigated is that light striking the retina may cause cellular damage and that this effect might be counteracted by dietary substances such as vitamin E and selenium, which belong to a class of compounds called antioxidants. Now the National Eye Institute's own clinicians are beginning a study to determine whether a reduction in light exposure, combined with antioxidant therapy, would in any way benefit people with aging-related maculopathy. I would like to stress that we do not at the present time have any evidence that light deprivation, or antioxidant therapy, can prevent human retinal degenerative diseases or affect the rate at which they progress; but this is an important research lead which we cannot afford to leave unpursued.

Another area of research dealing with the effects of light on the eye has been designated high priority. The hypothesis being explored is that prolonged exposure to light may damage the lens of the eye and contribute to the development of senile cataract. Cataract is an aging-related eye disorder that affects as many as 4 million Americans and is responsible for more than 500,000 eye operations each year. AS the average age of the population rises, senile cataract will become even more prevalent unless some means of prevention is found. For this reason, we are committed to investigating all possible leads to a solution of the cataract prevention puzzle.

In recent studies, light was implicated as a possible contributor to cataract formation. It was demonstrated that prolonged or intense exposure to ultraviolet rays like those in sunlight can cause chemical changes in lens proteins. The proteins turn a yellowish color and tend to clump together in large masses, disturbing the structure of the lens. Protein abnormalities of this sort have been observed other in animal lenses irradiated experimentally and in lenses from patients with senile cataract. Thus it appears that prevention of light-induced damage to the lens may be an important piece of the puzzle.

Another piece may be found in our aldose reductase inhibitor studies. As mentioned earlier, it has already been demonstrated that aldose reductase inhibitors can prevent the development of cataracts in diabetic laboratory animals. Since diabetics under 65 years of age are 3 to 4 times as likely to develop cataract as non-diabetics of the same age, confirmation of these results in humans would represent a significant advance in our ability to prevent at least one type of cataract.

All of this research on cataract prevention is of great importance economically. It has been estimated that a preventive measure effective enough to delay the development of cataract by only 10 years per patient would save the Nation $270 million a year in health expenditures.

One final area of vision research that I would like to highlight today in neurobiology. Two National Eye Institute grantees in this field, Drs. David Hubel and Torsten Wiesel, won the Nobel prize for their studies of how the brain processes visual information from the eye. Their work on visual experience in infancy has had great practical significance in the treatment of congenital cataract, amblyopia (lazy eye), and strabismus (crossed eyes), saving many children from needless visual loss by demonstrating that some visual problems must be corrected early in life if they are to be rectified at all.

Now other scientists supported by the National Eye Institute are also seeking ways to apply basic neurobiological concepts and techniques to the task of saving vision. One noteworthy effort is underway at the National Eye Institute's own clinical research facilities in Bethesda. Here neuroscientists and ophthalmologists are collaborating on the development of diagnostic techniques and new treatments for a wide variety of visual disorders that arise from abnormalities of brain function. An example would be nystagmus, in which the eyes exhibit rapid wobbling movements that can affect one's appearance and eyesight.

In my remarks today, I have tried to describe some areas of research that offer the greatest potential for preventing eye disease and visual disability. With a relatively modest investment of research dollars, they offer a good chance for alleviating human suffering and saving society literally billions of dollars. Now I would like to explain how we decide what research should be designated high priority.

The National Eye Institute has created and continues to employ a unique planning process. We collaborate with the National Advisory Eye Council and panels of expert consultants on a periodic in-depth study of vision research, taking stock of recent advances and identifying areas where there is the greatest need and opportunity for new research. The results of this study are incorporated into a three-volume report--a management tool that is used by the National Eye Institute's staff, the National Advisory Eye Council, and vision researchers as well. This plan serves as a stimulus to research in areas identified as high priority, areas such as the ones I have just described to you.

We have just completed our latest planning report and are in the process of publishing it. By planning and setting priorities, we are doing everything we can to make sure that funds for vision research are used as wisely as possible. Only in this way can we foster the new advances needed to lower the national toll of eye disease and visual disability.

In conclusion, Mr. Chairman, to continue support of these and other vision research activities in the coming year, the National Eye Institute's budget request for FY 1984 is $142,333,000. I will be happy to answer any questions you may have. Thank you.

Biography of Dr. Carl Kupfer

Name: Carl Kupfer, M.D.

Date & Place of Birth: February 9, 1928 - New York, New York

Citizenship: United States

Marital Status: Married

Education:

June 1945 - Graduated from High School
June 1948 - A.B., Yale University
June 1952 - M.D., The Johns Hopkins Medical School

Board Certification: American Board of Ophthalmology, 1958

Brief Chronology of Employment:

1952 - 1954	Internship and Assistant Residency, Wilmer Eye Institute The Johns Hopkins Hospital
1953 - 1954	Laboratory Assistant, Biostatistics, The Johns Hopkins School of Medicine
1957 - 1958	Research Fellow in Ophthalmology, Wilmer Eye Institute The Johns Hopkins Medical School Laboratory Assistant, Biostatistics, The Johns Hopkins Medical School
1958 - 1960	Research Fellow in Ophthalmology, Harvard Medical School
1960 - 1962	Instructor in Ophthalmology, Harvard Medical School
1962 - 1966	Assistant Professor of Ophthalmology Harvard Medical School
1966 - 1970	Professor and Chairman in Ophthalmology, University of Washington School of Medicine; Research Affiliate, University of Washington Primate Center
1970 -	Director, National Eye Institute National Institutes of Health

Military Service:

United States Air Force, November 27, 1954 - November 26, 1956

Societies:

American Physiological Society
Association for Research in Vision and Ophthalmology
American Academy of Ophthalmology
American Ophthalmological Society
Pan American Ophthalmological Society

Honors and Other Special Scientific Recognition:

Henry Strong Denison Scholarship 1949-1950
Consultant to Blind Babies Home, Boston, Massachusetts, 1962-1966
Program Director, Ophthalmology Training Grant, Massachusetts Eye and Ear Infirmary, 1962-1966
Member, Vision Research Training Committee, National Institutes of Health, 1963-1964
Member, Neurology Program - Project B, National Institutes of Health, 1967-1969
Member, Advisory Committee of Basic and Clinical Research, National Society for the Prevention of Blindness, Inc., 1968-
Editorial Board, Investigative Ophthalmology, 1969-1977
Clinical Associate Professor, Howard University, Division of Ophthalmology, 1970-
Editorial Board, American Journal of Ophthalmology, 1971-
Member, Scientific Advisory Committee, Fight for Sight, 1971-
Member, Scientific Advisory Panel of Research to Prevent Blindness, 1971-1974
The Secretary's Special Citation, Department of Health, Education, and Welfare, April 1972
Sanford R. Gifford Memorial Lecture, May 1972
The Superior Service Award, Department of Health, Education, and Welfare, May 1974
Ticho Memorial Lecture, September 1974
Member, National Diabetes Advisory Board, 1976
Migel Medal, American Foundation for the Blind, October 28, 1976
Edwin B. Dunphy Lecture, June 1977
Public Service Award in Ophthalmology, American Academy of Ophthalmology and Otolaryngology, October 1977
Speaker, Academy of Medicine of Washington, D.C., Winter Meeting 1980
Sixth Lorenz M. Johnson Lecture, April 1980
Principal Speaker for Friends of Eye Research, Rehabilitation and Treatment at the Helen Keller Centennial Congress, June 25, 1980
C. Dwight Townes Memorial Lecture, March 1981
Speaker, Medical College of Wisconsin Eye Institute Resident Alumni Meeting, June 1981
Speaker, Symposium on Basic Aspects of Glaucoma Research, Anatomic-Institute, University of Erlangen-Nurnberg, Germany, September 1981
Speaker, 35th Annual Congress of Japanese Clinical Ophthalmology, Juntendo University School of Medicine, Tokyo, Japan, November 1981
Speaker, Glenn A. Fry Award Lecture, American Academy of Optometry, December 1981
Senior Executive Service Bonus, 1981

Richard Stein Lecture, Maurice and Gabriella Goldschleger Eye Institute, Tel-Aviv University, Sackler School of Medicine, Israel, February 1982
Associate Examiner, American Board of Ophthalmology Oral Examinations, Philadelphia, Pennsylvania, April 1982
Johns Hopkins Society of Scholars, Johns Hopkins University, May 1982
Lecturer, Course in Community Eye Health, Institute of Ophthalmology, University of London, October 1982
Honorary Doctor of Science Degree, Scheie Eye Institute, University of Pennsylvania, November 1982
Member, Institute of Medicine, January 1983 - Present

International Appointments:

Member, Board of Trustees, Helen Keller International Incorporated, 1975-
Chairman, Projects and Priorities Committee, International Agency for the Prevention of Blindness (IAPB), 1975-
Coordinator for USA, US-Japan Collaborative Agreement in Vision Research, 1976-1982
Organizer, Oxford Assembly, IAPB, 1978
Member, International Vitamin A Consultative Group (IVACG), WHO 1973-
Visiting Professor, Pan American Ophthalmological Association, October 1975
Member of US Delegation to World Health Assembly, May 1978
Member, Advisory Group for Prevention of Blindness Programme, WHO, 1978-
Consultant, Pan American Health Organization (PAHO), 1978-
Temporary Adviser, WHO Task Force on Data on Blindness Meeting, Geneva, November 1978
Participant, Meeting on the Role and Functions of the National Institutes of Ophthalmology, Brussels, December 1978
Coordinator for USA, Priority Area "Eye Diseases," US-USSR Program for Health Cooperation, 1978-1981
Member, WHO Expert Advisory Panel on Trachoma and Prevention of Blindness, 1979-1984
Short-Term Consultant to Regional Office for South East Asia, WHO, New Delhi, India, December 1979-January 1980. Assignment to evaluate the Indian Plan for the prevention and control of blindness and to advise on training and research activities.
Consultant to WHO for Defining Guidelines for Blindness Prevention Programs in Africa, Bamako, February 24-27, 1980
Speaker, General Assembly of the World Council for the Welfare of the Blind, Antwerp, August 1979
Director, WHO Collaborating Center for the Prevention of Blindness, National Eye Institute, Bethesda, MD, 1979-
President, International Agency for the Prevention of Blindness, October 1982-Present

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Questions Submitted by the Subcommittee

INTRAMURAL RESEARCH

Question: Please explain why you wish to increase your Intramural research staff by nine (106 to 115) at an additional cost of $238,500. Why can't you do the research work for which you seek additional positions with the large staff you presently have?

Answer: One of the most important aspects of all NIH intramural programs is that they are uniquely suited to research projects requiring many years to come to fruition. We as a nation risk erosion of our science base if we restrict our support to projects which offer immediate results. We must also provide an environment conducive to long-term research projects, and the National Eye Institute's (NEI) intramural research program facilities offer just such an atmosphere.

The additional positions will be added to the NEI Intramural program to broaden its scientific expertise base so that full

advantage can be taken of the opportunities that abound in the Ambulatory Care Research Facility, such as research on eye movement, studies, neuro-ophthalmology, basic immunology, inflammatory diseases and gene-related research.

ALDOSE REDUCTASE

Question: Aldose reductase is an enzyme which is believed to be responsible for much of the tissue damage that occurs in people with diabetes. You have been working on drugs designed to block the action of the enzyme and help to prevent the development of cataracts in diabetic animals. Bring us up to date on your work with these "inhibitor" drugs.

Answer: In recent years, NEI scientists and several pharmaceutical companies have been developing and testing increasingly potent aldose reductase (AR) inhibitors. One of these is sorbinil, developed by Pfizer Laboratories. NEI scientists have shown that this drug completely blocks the development of cataract in diabetic laboratory animals. AR inhibitors have also been shown to prevent the development of cataract in animals with another metabolic abnormality called galactosemia. In addition, the drugs have been found to restore the capacity for normal healing of corneal wounds in diabetic animals. Another significant recent finding is that aldose reductase is present in the retina of the eye. This suggests that AR inhibitors may be of value in slowing down or halting the progression of diabetic retinopathy, the retinal disease that is the most frequent cause of blindness in diabetics.

Now, the NEI and the Pfizer Pharmacentical Company are collaborating to plan a clinical trial which will determine whether sorbinil can slow or prevent the development of diabetic retinopathy in insulin-dependent diabetics who are at high risk for the disorder. Pfizer will pay for about 95 percent of the costs of this trial.

Question: Would the "inhibitor" drugs have general application in treating diabetes?

Answer: The AR inhibitors show considerable promise as general agents to protect several of the body's tissues from the harmful effects of diabetes. In addition to showing potential as preventives for diabetic retinopathy and the premature cataract of diabetes, these drugs have recently been shown to be capable of partially reversing diabetes-caused nerve damage in human diabetics. This suggests that AR inhibitors may be valuable in combating diabetic neuropathy, a painful nerve disorder that occurs in many people with diabetes.

LASER TREATMENTS

Question: What is the status of laser treatment for diabetic retinopathy, a complicator of diabetes?

Answer: After a nationwide clinical trial supported by the NEI demonstrated the safety and effectiveness of laser photocoagulation as a treatment for diabetic retinopathy, use of this treatment has become more common. Laser photocoagulation is now employed throughout the country to treat people who are at risk of losing their vision from diabetic retinopathy. To gain additional knowledge

that can be used to protect the vision of diabetics, the NEI is now supporting another clinical trial involving laser treatment. This trial, the Early Treatment Diabetic Retinopathy Study, will determine whether laser treatment might yield even better results if it were used earlier in the course of diabetic retinopathy, before the patient has reached the advanced stage of the disease where the risk of blindness is greatest. Twenty-three medical centers around the country are participating in this study.

Question: About 62,000 Americans are legally blind from glaucoma and thousands of others have the disease. We understand that you are investigating laser therapy as one method to treat glaucoma. What success have you had with it?

Answer: Laser therapy is now being used to treat two types of glaucoma. In contrast to conventional surgery, laser treatment is a non-invasive outpatient procedure which may inconvenience a patient for only part of a day, after which he or she may resume routine activities. In the past few years laser iridotomy, which creates a small hole in the iris to relieve pressure build-up in the eye, has almost completely replaced the surgical procedure iridectomy to treat angle-closure glaucoma. If this treatment is administered promptly, it can permanently prevent loss of vision in affected eyes.

Argon laser trabeculoplasty, which facilitates outflow of fluid from the eye and lowers the pressure within the eye, has become an acceptable alternative to surgery in the treatment of severe open-angle glaucoma, which is the predominant form of this disease. The NEI is now sponsoring a controlled clinical trial to evaluate the efficacy and safety of laser trabeculoplasty as an alternative to life-long administration of drugs in the treatment of newly diagnosed glaucoma. This study is being conducted in seven clinical centers. Because laser trabeculoplasty has been used for only a few years, it is not yet possible to state what its long-term success rates will be for use at various stages of the disease, nor has it been determined which types of glaucoma patients will best be served by this procedure in preference to drugs or conventional surgery. The clinical trial and other studies should provide answers to these questions.

GLAUCOMA

Question: We understand that the prevalence of glaucoma in blacks, mainly males, appears to be 2-4 times higher than in whites and the disease seems to run a more severe course. What are the reasons for this?

Answer: Current data indicate that black males have a much higher prevalence of glaucoma and a more severe course of the disease than white males. At present, there is no explanation for these observations. Gaining knowledge about this problem is one of the priorities for research in the next five years identified in Vision Research--A National Plan 1983-1987. Improved epidemiologic data are needed to provide information on genetic/racial, socioeconomic, and environmental factors, both to define the extent of the problem accurately and to provide clues to its sources. NEI-sponsored studies of drug effects are also gathering data that should provide information relevant to treatment based on genetic/racial factors.

HERPES SIMPLEX INFECTIONS

Question: It's interesting to note that herpes simplex virus infections often produce irreversible changes in, and scarring of, the cornea. What steps are you taking to deal with this problem -- and what is the outlook for future success?

Answer: Ocular herpes simplex is the leading cause of corneal blindness stemming from infection, and research directed at its treatment and ultimate prevention is a major priority for the National Eye Institute. In FY 1982 the NEI funded 36 research grants involving herpes research at a total cost of $3.28 million. These included studies on the role of live herpes simplex virus and antigenic products in disease, and on neuronal factors responsible for viral neuronal latency and its role in recurrent disease.

Current research funded by the NEI also includes some studies concerned with developing and evaluating new antiviral drugs. The eye is an excellent model for determining the pathogenesis of herpes simplex infection and for developing effective methods to prevent and cure this disease. In fact, the first successful use of a drug in the control of any human viral infection was the introduction of idoxuridine for the therapy of ocular herpes. Virtually all of the antiviral drugs now commercially available for the treatment of generalized herpetic viral disease were originally tested and proved in the eye. Because of its excellence as a model of herpetic disease, the herpes simplex virus-infected eye continues to be used as a key laboratory screening device for a number of new antiviral agents now being developed and evaluated.

The outlook for the future includes a shift in emphasis in antiviral drug development toward developing drugs without the toxic side effects of those currently available while maintaining therapeutic efficacy.

Another hope for the future lies in research supported by the NEI and aimed at developing pure herpetic antigen for use as a vaccine. An experimental vaccine is being tested to determine if vaccination given early in life, before latent infection with live virus is established, can provide life-long protection.

INTER-INSTITUTE COLLABORATION

Question: To what extent do you coordinate your efforts with the Allergy Institute which also plays a leading role in research on herpes?

Answer: The extramural and intramural staffs of the NEI and the National Institute of Allergy and Infectious Diseases collaborate closely in areas of shared interests, such as herpes infections and ocular immunology.

The previous five-year vision research Plan expressed the need for expansion of immunological research on the visual system and its disorders. The Plan recommended that immunologists outside the vision field be encouraged to conduct research on ocular tissues and systems and that ophthalmologists take full advantage of the great expansion in immunologic knowledge and techniques now available. To this end, a series of three workshops was held as a joint effort

between the NEI and the NIAID and involved a collaborative effort of vision and nonvision scientists. Entitled "Immunology of the Eye," published reports from these workshops on the topics of "Immunogenetics and Transplantation Immunity," "Autoimmune Phenomena and Ocular Disorders," and "Infection, Inflammation, and Allergy" have been widely distributed.

In these reports a number of areas of research related to herpes were highlighted and recommendations were made by the workshop participants that these be explored and funded, including the use of mouse inbred strain models to study herpetic infection, genetically determined host resistance and susceptibility, new ways of tissue and fluid sampling for herpetic infections around the eye to find markers of the disease process, rapid diagnostic methods, and new, nontoxic antiviral drugs in treating stromal herpes and preventing herpes recurrence.

PROGRAM PLANNING ACTIVITIES

Question: Will the eradication of the herpes virus during its latent stage be a major priority of your new National Plan for Vision Research?

Answer: The ocular damage caused by herpes infection is due largely to its chronic recurrent pattern. An important research discovery made a few years ago was that reservoirs of latent herpes virus, which are the source of recurrent infections, exist in nerve tissue behind the eye. Vision scientists have now developed the first in vivo experimental system that makes it possible to study the process by which latent herpes simplex virus becomes active. The nature and mechanisms of herpes virus latency and reactivation are not completely understood at this time; better understanding of this problem is essential to further progress against ocular herpes infections. The new National Plan therefore identifies as a major objective the need "to investigate mechanisms of herpetic neuronal latency and the relationship of latency to herpes viral strains and patterns of disease; and develop further techniques for reactivation and suppression of neuronal reservoirs of chronically recurrent disease."

Specifically two areas of research have been designated in the Plan as Program Development Priorities. These are:

- Determine the neuronal and viral factors contributing to herpetic latency and the mechanisms that trigger viral reactivation and shedding.

- Develop highly specific, nontoxic antiviral drugs for topical and systemic use in treating infectious keratouveitis and in preventing recurrent disease by eliminating latent neuronal virus.

Question: You funded one or more Minority Biomedical Support Grants in Fiscal 1983 at a cost of $49,000, but do not plan for the same activity in Fiscal 1984. What is the reason for this?

Answer: The Fiscal Year 1984 revised budget now provides for $49,000 in this program.

MANAGEMENT CONTROLS

Question: At a time when many budgets are going down, Congress has been increasing funding of the National Institutes of Health including your Institute. We are concerned that these scarce resources be carefully and effectively used and that there be no basis for criticism of your management of this money. What assurances can you give us that your Institute is making careful and effective use of the appropriations we provide you?

Answer: To ensure that the resources we receive from the Congress are used as effectively and economically as possible, the NEI has made research planning the strong foundation upon which our research program decisions are made. This planning effort has most recently resulted in a document, Vision Research--A National Plan: 1983-1987, which spells out program goals and objectives, identifies research needs, opportunities, and priorities, areas where chances for sight-saving discoveries are greatest. The National Advisory Eye Council (NAEC) will use this document to identify program activities as well as individual grants that are the most worthy of support.

In addition the NEI has established a small-grant program for pilot projects with maximum direct cost of $15,000. While the initial purpose of the program was to attract individuals with limited research experience and to attract innovative research proposals, the program has the added advantage of being cost effective in that the application form has been simplified and therefore takes less time to fill out and can be more rapidly reviewed by Institute staff.

Question: Aside from the peer review system, what institutional arrangements do you have that serve to deter waste, fraud or abuse in the handling of federal funds?

Answer: The NEI staff routinely reviews all grant applications to make certain that all requests are within established regulations and guidelines. They review the level of support requested to ensure that Institute policies are adhered to.

The NEI has established procedures for approving and monitoring the requested operating level of in-house programs, such as Intramural Research, Direct Operations and Program Management. Within the Intramural Program, section chiefs prepare a requested funding level; the request is then reviewed by the laboratory chief, administrative staff, Scientific Director and the Executive Officer to ensure that the support requested is proper and necessary. The approved level of funding is then monitored throughout the year. A similar procedure is followed for Program Management and Direct Operations.

BUDGET ESTIMATES

Question: There's more to the revised NIH budget than simply the specific cuts we've just discussed. There are effects, as well, and they represent an important form of reduction.

For example, the January budget first, and now the April budget, assume cuts in the average award for new and competing grants below what the full average cost should be. For new grants this appears to

be a difference of some $17,800 ($142,400 for the full cost vs. $124,600 in the revised budget). How will this reduction in the average cost of grants affect your Institute -- and, most importantly, to what extent will it change the scope and quality of the projects that are reviewed by your study sections?

Answer: The January and April budgets do assume cuts in the average award for new and competing research grants from the NIH computer model's projections of study section recommendations for 1984. However, the amount budgeted for new and competing research project grants in the April budget still includes an increase in the average cost of these awards over the 1983 average cost of about 4 percent for NEI. Even when this increase is offset by the proposed reduction in indirect costs from 1983 to 1984, the 1984 average cost is still an increase over the 1983 average cost.

For NEI the reduction in the average cost of competing grants to which you refer is about 17 percent compared to the projected study section recommendations for 1984. This may mean that the progress towards project related-goals as well as our overall NEI program goals will move at a somewhat slower pace.

Question: We understand the noncompeting continuation grants will get similar treatment, with the average grant award projected to decrease by about $12,400 below the full average costs ($143,199 full cost vs. $130,700 in the budget revision). Once again, what's the effect on your Institute -- and what will this do to the scope and quality of the projects that are reviewed by your study sections?

Answer: The reduction in the average cost of noncompeting grant awards is about 10 percent for the NEI. In ongoing projects, the rate of progress may be slowed, and the time allotted for completion of the originally proposed and funded research may need to be extended. Even with this reduction, the 1984 budget includes an increase in the average cost of non-competing awards of about 7 percent for NEI offset by the indirect cost reduction of 3 percent which results in a net increase of about 4 percent from 1983 to 1984.

PROGRAM PLANNING PRIORITIES

Question: We understand the new National Vision Research Plan will soon be published and will be the guide for development of your program over the next five years. What priorities will the new Plan set?

Answer: The Plan defines various kinds of priorities. For example, NEI's highest priority research goal is the prevention of major blinding and disabling eye diseases. The highest priority NEI support mechanism is the individual, investigator-initiated research project grant (R01). Within each of the NEI's five major programs, and for the special cross-program category of Visual Impairment and Its Rehabilitation, the Plan outlines a number of Program Development Priorities. The latter are defined as areas of ongoing research in which new knowledge and techniques offer particular opportunities for scientific progress, or promising new areas of research in which there is little or no support at present, but where there is both great need and high potential for success. Such areas are judged to warrant significantly increased support over the next five years, provided that high quality

applications for research grants are submitted. The following are examples of the Plan's recommended Program Development Priorities:

Retinal and Choroidal Diseases

- Exploiting technological advances in the fields of molecular biology, cell physiology, and tissue culture for basic research on retinal cells and tissues.
- Assessing new drug and immunological approaches to the treatment and prevention of uveitis and other inflammatory disorders.
- Expanding biochemical and metabolic studies of various retinal tissues to provide new insights into aging-related maculopathy, other retinal degenerations, and retinal detachment.
- Intensifying the search for biochemical and genetic defects in retinitis pigmentosa and other hereditary retinal degenerative diseases, utilizing new molecular biology techniques.
- Characterizing neurotransmitters, the chemical substances that relay messages from one retinal nerve cell to another, with the aim of developing drug therapies for retinal neural disorders.
- Performing studies of retinal capillary cells in tissue culture to elucidate the mechanisms involved in diabetic retinopathy, sickle cell retinopathy, and other vascular disorders.
- Conducting basic research on retinal detachment.
- Assessing the damaging effects of environmental factors, nutritional deficiencies, and drugs on retinal function, and developing screening systems for ocular toxicity.
- Pursuing new approaches to research on sight- and life-threatening intraocular tumors.

Corneal Disease

- Determining the neuronal and viral factors contributing to the latent period of ocular herpes infection.
- Continuing development of antiviral drugs for treatment of acute and recurrent corneal infections.
- Continuing development of methods to stimulate repair of the diseased or injured corneal endothelium (the tissue's innermost layer), especially in primates, and improving corneal transplant procedures using cultured endothelial cells as a possible replacement for donor tissue.
- Studying the biological effects of existing and proposed surgical procedures and optical devices for correcting refractive error.

- Evaluating immunological mechanisms of the ocular surface and their role in health and disease.

- Studying the frequently painful abnormalities of the ocular surface.

- Improving understanding of the biochemical and immunological components of the cornea's response to injury and wound healing, determining the importance of specific immunological factors in corneal transplantation, and developing and testing drugs that can modify or eliminate damaging immune reactions to transplanted tissue.

Cataract

- Determining through epidemiologic studies factors that increase one's risk of developing cataract.

- Studying the molecular biology of the normal lens and cataract.

- Developing an objective system for classifying cataracts in the living eye as a standard for research on cataract prevention and treatment.

- Studying the potentially cataract-inducing effects of low doses of ionizing and microwave radiation and the effects of environmental ultraviolet radiation on the lens.

- Comparing the results of various methods of cataract surgery and employing controlled clinical trials to determine the safety and efficacy of various methods of optical correction following cataract surgery, including intraocular lenses, contact lenses, and surgical modification of corneal curvature.

- Conducting further studies of the characteristics of the enzyme aldose reductase and developing safer and more effective aldose reductase inhibitors to delay diabetic cataract formation.

Glaucoma

- Conducting clinical and laboratory studies to define genetic, racial, and environmental risk factors for the development of damage to the optic nerve in glaucoma and to determine the reasons for the varying susceptibilities of individual eyes to optic nerve damage.

- Developing improved methods of detection and diagnosis and better drug and surgical treatments for glaucoma.

- Devising new noninvasive clinical techniques for studying aqueous humor formation and flow, for continuous monitoring of intraocular pressure in man and in primates, and for studying experimental optic nerve damage in monkeys.

- Studying the cell biology and molecular characteristics of the outflow tissues and their abnormalities in glaucoma, especially using tissue and organ culture techniques.

- Exploiting experimental methods of studying the basic physiology and pharmacology of fluid movement in the eye and of controlling aqueous humor inflow in primates and in man.

- Investigating neovascular glaucoma which results from the formation of abnormal blood vessels on the iris that overgrow the angle, often occurring as a severe complication of certain retinal vascular diseases, and developing methods for its treatment.

Strabismus, Amblyopia, and Visual Processing

- Developing new or improved techniques for treating strabismus, including surgical, pharmacological, or other approaches.

- Developing and evaluating new treatments for amblyopia.

- Devising noninvasive methods for studying the development of visual processing in infants, particularly methods that could be used in the clinic for diagnosing and monitoring the effects of treatment.

- Studying the normal development and control of the eye movement system and the disorders that may affect it, especially using techniques that will aid in diagnosing eye muscle problems in newborns and young children.

- Determining the causes of and mechanisms responsible for the development of myopia in humans.

- Investigating the structure, function, and development of the visual system at the molecular level with the ultimate aim of designing drug treatments for visual neurosensory disorders and injuries.

- Studying the anatomy, physiology, and behavior of the systems that are important in vergence (moving the two eyes toward or away from each other to look at a nearby or distant object) and accommodation (changing the shape of the lens to allow the eye to focus on an object) in normally developing infants as well as in those at risk for strabismus.

- Exploring the etiology of optic neuritis and optic nerve atrophy and those factors that may permit regeneration of the diseased or injured optic nerve.

Visual Impairment and Its Rehabilitation

- Defining the visual characteristics of individuals with specific types of visual impairments.

- Conducting research on the optical, electronic, and other rehabilitative needs of visually impaired persons.

- Conducting research on improving basic skills relating to mobility and visual orientation in the low vision population.

- Encouraging human engineering studies that will help people with specific impairments interact more independently with their environment.

- Conducting epidemiological studies of the types and extent of visual impairment resulting from a variety of disorders.

- Developing aids, including contact lenses and other specialized lenses, for patients with corneal or lens problems.

- Studying the effects of prior visual experience upon the nature and extent of visual impairment in young children and on their ability to function despite such impairment.

NEW PRIORITIES

Question: How will your new priorities differ from those in the previous five-year Plan?

Answer: In many cases the priorities in the new Plan will be similar to those in the previous Plan, although in several instances they have been modified to accommodate recent scientific and technological advances that are applicable. Some priorities from the previous Plan have been dropped entirely, either because they have been fulfilled or because their original promise was not borne out by actual experience. Most of the priorities in the new Plan, however, are entirely new, reflecting broadened scientific input into the planning process, which has provided new perspectives on research needs and opportunities, and the many discoveries which have been made in vision and other fields of science during the past five years. The NEI will be closely monitoring the implementation of the new Plan by tracking grant applications and keying them to priorities in the new Plan. Data on approved and disapproved, and funded and unfunded grants will be captured and periodically analyzed to determine how well the plan's recommendations are being fulfilled. As a result of this analysis, the NEI may make an additional effort to encourage the submission of grant applications in certain priority areas. In some instances, the priorities themselves may be modified, if necessary. When it is time to prepare the next five-year Plan, such data will weigh heavily in determinations of revised and new research priorities.

CONSTRUCTION, RENOVATION AND BIOTECHNOLOGY RESOURCES

Question: Your justification indicates you spent $5 million in Fiscal 1982 for construction in the vision field. What was this money used for -- and have all of the funds appropriated been spent?

Answer: The Fiscal Year 1980 appropriation included $3 million for an NEI construction grant program. These funds, available until expended, were provided to increase the availability and to improve the quality of vision research facilities. All of these funds have been obligated. In addition, the NEI obligated $2 million from

Fiscal Year 1982 appropriated funds to support the construction grant program.

Awards were made to the following institutions: University of Miami, University of Michigan, University of Missouri, University of Illinois, Estelle Doheny Eye Foundation, University of Southern California, Boston University, University of Rochester, Johns Hopkins University, New England Medical Center Hospital, Medical College of Wisconsin, Emory University, Rockefeller University, University of California, San Francisco, and Oakland University.

Question: To what extent is there further need for replacing or adding to vision research facilities in the field?

Answer: Professional and private groups interested in vision research have described the need for construction of clinical research facilities. In testimony before the House Subcommittee on Appropriations for the Fiscal Year 1981 appropriations, a spokesman for Research to Prevent Blindness, Inc. identified adequate and increased research space as a key concern. In 1982, the NAEC passed a resolution stressing the importance of government support for the construction of clinical research facilities.

The NAEC further documented its interest in additional support for construction in Vision Research--A National Plan: 1983-1987. In each NEI program, needs and opportunities for research aimed at improving the diagnosis and treatment of eye diseases have been identified along with opportunities for research, which may eventually lead to means of preventing such disorders. In particular, numerous opportunities for clinical research and clinical trials have been documented for such disorders as strabismus, amblyopia, retinal degenerations, corneal diseases, glaucoma, and cataract.

The need for specialized, expensive items of new technology in vision research is great. Vision researchers receive only a small portion of overall NIH biotechnology resource funding because their research is so specialized. Vision research with its use of lasers, electronic eye tracking monitors and other specialized research equipment is in the forefront of applying technological advances to research programs.

COLLABORATION OF INSTITUTES

Question: Your research work seems to take you into areas that could provide useful information for other Institutes of NIH. You do work on diabetes, herpes and the neurosciences. To what extent do you coordinate these efforts with the other NIH Institutes -- and provide them with research results?

Answer: In all three of the areas mentioned, the NEI has been collaborating actively with other institutes of the NIH. The NEI has played an active role in the National Diabetes Advisory Board, the trans-NIH Diabetes Coordinating Committee, and the government-wide Diabetes Mellitus Interagency Coordinating Committee. These groups have been established to improve the coordination of Federal research and health care programs. Some examples of our coordinated efforts through these groups are as follows:

- The NEI program director for diabetic retinopathy co-chaired with the director of the NIADDK Diabetes Division a symposium on appropriate animal models for the study of diabetes and diabetes complications.

- NEI researchers, together with representatives of other institutes, have participated in the development of a handbook for physicians, The Prevention of Five Complications of Diabetes--A Guide for Primary Care Practitioners. A major portion of this guide, which deals with the prevention of ocular complications of diabetes, is predicated on the positive results of the NEI's Diabetic Retinopathy Study.

Our cooperation with other institutes concerning eye complications due to diabetes is perhaps best exemplified by our close participation with the NIADDK in designing, developing, and monitoring their multi-center Diabetes Control and Complications Trial. The primary outcome being evaluated in this multi-center clinical trial of the effects of control of blood sugar levels on diabetes complications, is diabetic retinopathy. NEI staff have assisted in the development of study design, have helped in the planning for eye exams, and are participating in the policy, data, and safety monitoring for the study.

There has also been close cooperation between NEI and NIADDK in the dissemination of the results of the NEI's Diabetic Retinopathy Study (DRS) to patients with diabetes and to primary care practitioners. The DRS demonstrated that laser photocoagulation treatment can reduce by 60 percent the chance that people with advanced diabetic retinopathy will suffer severe visual loss. The NEI has prepared a number of fact sheets and a brochure called "Diabetes and Your Eyes" which explains how diabetes affects the eyes, and how the risk of visual loss can be reduced. The NIADDK has participated in the distribution of these materials to patients and their families through the National Diabetes Information Clearinghouse.

In the area of the neurosciences, the NEI participates actively in an interagency working group on this subject that meets monthly on the NIH reservation. Representatives of the National Institute of Neurological, Communicative Disorders and Stroke, the National Institute of Child Health and Human Development, and the National Institute on Aging participate in this group, in addition to representatives of the National Science Foundation, ADAMHA, and the DOD.

The function of this working group is explicitly to coordinate the various institutes' efforts in funding research in the neurosciences and to share important results emanating from our grantees' work. The group recently sponsored a joint symposium on Federal funding in the neurosciences at both the Society for Neuroscience Annual Meeting (November 1982) and the Winter Conference on Brain Research (January 1983). One entire meeting of the interagency group was devoted to the research plan formulated by the NAEC to establish the most promising directions for research to be supported by the NEI over the next five years. The Plan discusses areas of complementary research in the neurosciences supported by the other institutes at NIH as well as other public and private agencies.

The extramural and intramural staffs of the NEI and the National Institute of Allergy and Infectious Diseases collaborate closely in areas of shared interests, such as herpes infections and ocular immunology. The NEI's interest in such collaboration was strengthened by the previous five-year vision research Plan, which expressed the need for expansion of immunological research on the visual system and its disorders. The Plan recommended that immunologists outside the vision field be encouraged to conduct research on ocular tissues and ocular systems and that ophthalmologists take full advantage of the great expansion in immunologic knowledge and techniques now available. To this end, a series of three workshops was held as a joint effort between the NEI and the NIAID and involved a collaborative effort of vision and nonvision scientists. In published reports from these workshops a number of areas of research related to herpes were highlighted and recommendations were made that these be explored and funded. The areas include the use of mouse inbred strain models to study herpetic infection, investigation of genetically determined host resistance and susceptibility, finding new ways of sampling tissue and fluid from herpetic infections around the eye to find markers of the disease process, devising rapid diagnostic methods, and development of new, nontoxic antiviral drugs in treating stromal herpes and preventing herpes recurrence.

As a result of the workshops there has been a significant increase in multidisciplinary collaboration in this field, and in the conduct of immunology-related vision research by people who had not previously been involved in vision research. Many more grant applications have been received and funded by the NEI from both groups of researchers.

PREVENTION

Question: You state that "at present, few of the major eye disorders can be prevented." Why is this so--and does it indicate you're not devoting enough of your effort to prevention?

Answer: Unfortunately, the leading causes of blindness and severe visual impairment in the United States--glaucoma, macular degeneration, senile cataract, optic nerve atrophy, diabetic retinopathy, uveitis, and retinitis pigmentosa--are chronic, slowly progressive disorders, whose causes are unknown but which are most likely multiple and complex. As a result of NEI-supported research, major accomplishments have been made over the past decade and continue to be made in the improved diagnosis, treatment, and amelioration of these disorders. During the same period, knowledge of the basic mechanisms underlying these problems has greatly expanded as a direct consequence of increased NEI support for laboratory and clinical research.

The NEI has made research that could lead to the prevention of eye disorders and diseases one of its primary goals. A review of the research objectives in virtually every section of the new National Plan will demonstrate recognition of the importance of prevention of eye and vision diseases and disorders. In fact, a great number of the Plan's Program Development Priorities encourage research that is prevention-related. Currently, approximately one-third of the NEI budget supports research that is aimed at the ultimate prevention of eye disease or its sequelae: visual impairment, disability, and blindness. In FY 1982, the NEI supported 355 research projects

related to prevention, at a total cost of $36.0 million. An estimated $40.9 million will be spent on prevention-related vision research in FY 1983.

KNOWLEDGE TRANSFER

Question: You completed a clinical trial last May which showed that laser treatment can be used to prevent vision loss from a disease (maculopathy) which affects millions of people over age 50. How have you followed up this clinical trial to make sure doctors are alerted to the problem and the possible use of laser treatment?

Answer: The NEI has made great progress in disseminating the results of the Senile Macular Degeneration Study (SMDS). Copies of the study's findings have been sent to all ophthalmologists and optometrists in the country, and major publications in the fields of eye care and aging have been provided with the materials they need to run articles on the study. In addition, coverage of the study has been obtained in newspapers, national magazines, television news programs, and television documentaries. Through these activities, the NEI has conveyed the study's findings to large numbers of health care professionals as well as the general public. We plan to continue these information activities in the future to achieve even wider dissemination of the SMDS results.

CATARACT TREATMENT

Question: Your justification makes a good point in stating that those who have been treated surgically for eye cataracts "would have preferred to have avoided....surgery altogether." Undoubtedly, a lot of those folks are elderly. What progress are you making toward preventing or slowing cataract development -- or for treating it non-surgically?

Answer: There is no proven medical treatment that will prevent or cure most forms of cataract, the third leading cause of blindness in the United States. The only effective treatment is surgery--employed when a cataract becomes visually disabling--in which the clouded lens is removed from the eye through an incision in the cornea or sclera.

Development, and subsequent evaluation, of a promising non-surgical method of preventing and treating human cataract is one of the most difficult challenges in ophthalmology today. However, years of careful and well-documented basic research on cataract have led to the identification of inhibitors of the enzyme aldose reductase (AR) as potential agents for preventing certain types of cataract resulting from defects in sugar metabolism, such as diabetes. A highly significant recent finding was that AR inhibitors are effective in reversing neuropathy in diabetic patients. This finding is the first evidence in humans that AR inhibitors may alter the course of diabetic complications in tissues outside the eye. The next phase will be to plan for a clinical trial of the AR inhibitor sorbinil in diabetic retinopathy. Research on diabetic and other metabolic cataracts is relevant not only to other areas of cataract research, but to vision research and biomedical research in general. For example, this research has a bearing on studies of the normal lens and on congenital and senile aging-related cataracts. The relationship of cataract research to the problems of aging is also apparent.

However, until the pathways to aging-related cataract formation are more fully understood in the laboratory, and the appropriate methodology developed for evaluating promising drugs or agents in animal models and in man, it will be difficult to develop non-surgical means of prevention or treatment.

Question: The Cooperative Cataract Research Group, composed of scientists from 23 institutions, was formed in 1978 to speed up lens research related to cataract problems. To what extent has the group made advances in human cataract research?

Answer: The Cooperative Cataract Research Group (CCRG) has established a system of classifying cataractous changes in the human lens by a standardized photographic procedure. It is now possible to correlate medical histories with specific classes of human lens opacities. These procedures also make possible the study of the morphology and chemistry of human cataract in a rational way. The morphology of specific individual opacities, as seen in the freshly extracted human lens can be correlated with their ultrastructure by scanning and transmission electron microscopy and by chemical composition through energy dispersive X-ray analysis (EDXA). EDXA in conjunction with scanning electron microscopy (SEM) was used to analyze and compare clear and opaque areas in a group of human cataractous lenses that contained small, scattered, localized opacities. These areas of opacification were clearly seen in the CCRG stereo slides made of each lens while fresh. EDXA analysis of these opacities showed a high concentration of phosphorus and little or no sulfur. Analysis of the normal appearing lens fiber immediately adjacent to an opacity indicated that this area, in contrast, contained very little phosphorus but large amounts of sulfur. This is an example of how the researchers in this field are trying to understand the nature of the changes that occur in the lens when a cataract forms.

INTER-INSTITUTE COOPERATIVE EFFORTS

Question: What cooperative efforts, if any, are there between the Eye and Aging Institutes to research biochemical processes in aging that may explain eye diseases common to the elderly?

Answer: A great many diseases and disorders of the eye are associated with aging. Increasing national concern for vision problems of the elderly led recently to the convening of two White House conferences. The National Institute on Aging had a major responsibility for the planning of the conferences and the NEI assisted them in their efforts. The first was a "mini" White House Conference on Vision and Aging, held in January 1981 at the request of the White House Conference on Aging by the American Foundation for the Blind and 15 co-sponsors. Participants in the conference generated a preliminary list of recommendations for the White House Conference on Aging held in November/December, 1981. These recommendations were made in six areas: public education, rehabilitation and treatment, low vision and public policy, professional education and professions, research, and financing and legislation.

In a effort to share research resources, aged rhesus monkeys maintained by both institutes are currently used for NEI-sponsored research involving presbyopia (a visual condition affecting the ability of the eye to focus sharply for near vision).

Questions Submitted by Senator William Proxmire

Question: On page 101 of your justifications you state that the 1984 request for program management remains the same as 1983, yet the material on page 124 shows a $14,000 increase. Could you reconcile this conflict?

Answer: When computing the continued costs of so-called "in-house" programs, there are a variety of expenditures, for example, within-grade increases, NIH Service and Supply Fund, Federal Employees Compensation Fund, and the Management Fund--also referred to as mandatories--which must be paid. In fact, there is a $14,000 increase for Program Management above the Fiscal Year 1983 level for these mandatories.

LASER TREATMENT

Question: Dr. Kupfer, in your prepared statement you indicate that a new laser treatment could prevent blindness in 13,000 older Americans each year and save $57 million annually. Just to place these impressive savings in context, can you tell us how much it would cost each year to provide this treatment to 13,000 older Americans?

Answer: In order for the full sight-saving potential of the newly evaluated laser treatment to be realized, it is assumed that this therapy is offered to all 200,000 people who are in danger of losing their vision from the neovascular form of aging-related maculopathy. Thus the group of people receiving the treatment would include not only the 13,000 who are destined to go blind without it, but also a much larger number who are now at high risk of losing vision in one eye. The cost for treating all 200,000 people would be $27 million. If the laser procedure is not used, the cost to society of maintaining the 13,000 people who go blind for lack of treatment would be $84 million. The net savings from treatment would thus be $57 million.

Question: How close are we to the routine use of this laser treatment to prevent blindness?

Answer: Since the NEI announced the findings of the Senile Macular Degeneration Study that it supported, the use of laser treatment for the neovascular form of aging-related maculopathy (or senile macular degeneration) appears to have greatly increased nationwide. Several factors have contributed to the rapid adoption of the technique. One is that the NEI sent the study findings to every ophthalmologist in the country, thus making certain that they could immediately use the information to benefit their patients. Another important factor is that virtually all university departments of ophthalmology, along with many hospitals and ophthalmologists in private practice, already have the diagnostic equipment and ophthalmic laser needed to offer the treatment. Also, the release of the study findings has stimulated universities and professional organizations to offer training courses for ophthalmologists seeking more information about the laser technique.

Taking all these factors into consideration, it is clear that there has been great progress in the dissemination of knowledge about laser treatment of aging-related maculopathy, and the time is rapidly

approaching when all patients who might benefit from the procedure will routinely be considered for it.

Question: When will the laser be routinely used to treat diabetic retinopathy?

Answer: Ophthalmologists now make routine use of the laser when it comes to treating patients with diabetic retinopathy. The problem is that other health care providers, and the general public, are not sufficiently aware that diabetes can cause blinding eye disease, that a treatment is available, and that regular eye examinations are needed to determine when laser treatment has a chance of saving sight. It is for these reasons, that HHS selected the NEI diabetic retinopathy knowledge transfer/information dissemination campaign as an important disease prevention health promotion initiative.

To date, the NEI has worked with many organizations and professional societies concerned with diabetes and blindness prevention on the development and distribution of information materials. In addition, NEI has produced and widely distributed a brochure called Diabetes and Your Eyes. The brochure has been so well received that several private organizations are reprinting the brochure at their own expense; several million copies are expected to be printed and distributed by organizations in the private sector.

We plan to continue this information campaign in the hope that information about diabetic retinopathy and its treatment can be spread so widely that all people in need of laser photocoagulation will receive it as a matter of course.

FUNDING EMPHASIS

Question: According to the budget submitted to the Committee within the last few days you plan to spend $11,771,000 on new competing research grants in 1984, isn't this so?

Answer: Yes, the NEI will support 125 new competing research project grants in 1984.

Question: In comparing your 1982 actual figures with your 1984 request, I note that over this two year period funding for noncompeting research grants would increase by 18.4 percent while support for new competing grants would increase by only 6.1 percent. This would seem to indicate you are placing a lesser emphasis on new innovative work. Could you explain this pattern to the Committee?

Answer: The highest quality and highest priority science in the vision research field is identified in the competitive process. Since both competing and noncompeting grants were selected as a result of the competitive peer review process, we believe both support new innovative work.

Grants now categorized as noncompeting were actually competing research grants one or two years ago. As such they were subject to Study Section and NAEC review, as well as grants management scrutiny. While the budget period of competing research grants may be for three years, and they are subject to peer review only the first year, they are also reviewed by NEI staff on a yearly basis so that if their progress reports are not satisfactory or their budgets change

drastically, such matters can be considered before they are paid as noncompeting research project grants.

New competing research project grant applications are first-time applications and are subject to peer review as was mentioned.

INTRAMURAL RESEARCH

Question: You are requesting an additional 9 positions for the conduct of intramural research in the Ambulatory Care Research Facility, particularly for research on eye movement studies, neuro-ophthalmology, basic immunology, inflammatory diseases, and gene-related research. What factors entered into your decision to expand your intramural research in these areas rather than provide additional support through the research grant mechanism?

Answer: The areas of the intramural program which are being expanded are those in which the scientific expertise and/or interest exist primarily in the NEI intramural research. Often the outside community does not submit grant proposals to pursue all important, high priority areas of vision research. In addition, the existing multi-disciplinary intramural staff provide an opportunity to explore clinical and laboratory investigations together.

The NAEC in its Vision Research--A National Plan: 1983-1987 acknowledged the unique role of NEI's intramural program in helping to carry out the priorities of this plan and in serving as a national resource for the training and career development of basic and clinical vision researchers. The clinical research facilities in the new NIH Ambulatory Care Research Facility will permit the NEI to place even more emphasis on direct clinical research training activities and the relationship of basic to clinical research.

One of the most important aspects of all NIH intramural programs is that they are uniquely suited to research projects requiring many years to come to fruition. We as a nation risk erosion of our science base if we restrict our support to projects which offer immediate results. We must also provide an environment conducive to long-term research projects, and the NEI's intramural research program and facilities offer just such an atmosphere.

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

STATEMENT OF DR. DAVID P. RALL, DIRECTOR

ACCOMPANIED BY:

PAUL G. WAUGAMAN, EXECUTIVE OFFICER, NIEHS
DR. JAMES B. WYNGAARDEN, DIRECTOR, NIH
H. RICHARD MILLER, ASSISTANT DIRECTOR, DIVISION OF FINANCIAL MANAGEMENT, NIH
ANTHONY ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET, DHHS

BUDGET REQUEST

Senator WEICKER. Next, we will hear from the National Institute of Environmental Health Sciences, which does research on the pollutants and toxic substances which threaten our environment.

The Environmental Health Sciences Institute is located in North Carolina and is the only Institute of NIH which is outside of Washington.

Your revised 1984 budget request is $165.8 million for the Institute which is $837,000 less than the January request. And the new request is $1.5 million above the 1983 level.

Here to testify on behalf of the Institute's budget is the Director, Dr. David Rall.

Dr. Rall, please proceed.

INTRODUCTION OF ASSOCIATES

Dr. RALL. Thank you very much, Mr. Chairman.

Let me introduce on my left Mr. Waugaman, our Executive Officer.

We are indeed located in North Carolina. And I brought along some photographs to show our new, modern, efficient, and very safe laboratory and office complex.

OPENING STATEMENT HIGHLIGHTS

Senator WEICKER. How did you luck out in getting out of this town?

Dr. RALL. It was a wise decision made by the Congress in 1961 when they put in the appropriation language that we must be located at least 50 miles away from metropolitan Washington, D.C.

NIEHS is a noncategorical institute in that we are not associated with any group of specific diseases, but we instead try to look at the effects of the environmental factors, physical and chemical, on human health. We are a research institute, not a regulatory agency.

The research results that we produce are shared with other scientists and other institutes. The toxicity of the chemicals that we study impinge upon many of the diseases that concern other institutes. And so we constantly coordinate our programs with them.

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Our research results are of interest to physicians in treating patients and are of major interest to the various health regulatory agencies such as FDA, OSHA, CPSC, and EPA.

And finally, we make a conscious effort to disseminate the results to the public so that they can understand what we are doing and they can also understand and make judgments on their own as to the safety of compounds with which hey come in contact.

We conduct research in our own laboratories and support in outside laboratories a full spectrum of research and development activities. These range from very basic research such as the mechanism of genetic mutations and chromosome alterations—which is really part of the biological revolution that was discussed here yesterday—to the actual pragmatic testing of chemicals for toxicity to insure that people are not exposed to hazardous chemicals.

And finally, we do epidemiological studies in which we try to look at groups of people who have been exposed to potentially hazardous chemicals to see what health effects may have occurred.

Now, in the basic research part, the concept of understanding the mechanism of action of the chemicals we study is terribly important. If you understand their mechanism of action, you can then much more easily move on to prevention, to treatment, and even to regulatory activity.

Let me illustrate the importance of this basic research from our personal experience. I remember when I was growing up, I was always told that although the west coast of South Africa and the east coast of South America fit together just perfectly on a map, the data told us that continents can't drift. And so, of course, the fit was just a coincidence.

The new theories of plate tectonics in Earth sciences have changed that viewpoint. It seems to me scientists believe theories and want the data to fit the theories. So in environmental health research, we strongly believe mechanism studies that provide the basis for new theories are very important.

For instance, one of our scientists has recently completed some elegant research showing that asbestos fibers—which in human beings cause pulmonary fibrosis, lung cancer, and other tumors—actually penetrate the cells in the lung. And in so doing, they damage the chromosomes of the cells. And later, it can be shown that these cells are transformed from normal to malignant cells.

This allows us, then, perhaps to test other chemicals in this same manner to see if they have similar toxic effects. And we can prevent exposure of people to these various chemicals.

Now, beyond test development, we also do something that we call test validation which we think is enormously important. And it tends to be neglected by the academic community. We want to be sure that the tests that are developed actually do predict what happens in experimental animals and ultimately in human beings.

If the tests predict chemicals are nontoxic, it is important they really be nontoxic and vice versa.

In terms of our testing activities at the moment, we have about 170 compounds under test for long-term toxicity in laboratory animals. About 300 chemicals, including many of the 170, are being evaluated in short-term tests for mutational toxicity. And in addition, we have about 100 other ongoing tests for general toxicity.

And finally, to complete the spectrum since ultimately we are concerned about what happens to people, we have a number of epidemiological studies ongoing. One of the most interesting is a long-term prospective study of about 900 children born in North Carolina in the past 4 or 5 years.

We have obtained samples of blood and milk from the mothers of these children. We can analyze those samples to determine what environmental pollutants are in the mothers' milk and in the blood, how much PCB, DDT, and so forth. We know which children are breast fed and, therefore, which got larger amounts of these pollutants through mother's milk.

The oldest child is about 4 years old. They all look fine, we are very happy to say, but we will follow this group of children in whom exposure to environmental pollutants has been carefully documented for many years to insure that there are no hazardous effects.

Mr. Chairman, I hope this gives you an overview of NIEHS.

GRANT FUNDING

Let me now spend a moment or two on your list of questions for each Institute Director.

We have in terms of the decreased noncompeting and the negotiation of the awards always done this. Our staff deals directly with the scientists and administrators, and we negotiate mostly down, occasionally up. I have talked to scientists out in the universities to whom we award grants, and they are comfortable with the extent of downward negotiation that we are currently doing.

Yesterday, you asked about the tradeoff between a greater number of inexpensive grants versus fewer fully funded grants. And there is no question in my mind that the grants have to be adequately funded. This doesn't mean they need every dollar that they request. But I think it would be a mistake to try to award more grants, get a bigger number, and inadequately fund those which you do award.

So within certain limits, I think a gentle downward negotiation is quite appropriate. And according to the scientists I talk to, they are very comfortable with it.

In achieving our share of the 5,000 new and competing grants, we were more gentle with our centers than most of the other institutes because we feel environmental health research is quite interdisciplinary. The best way you can do this research is to have interdisciplinary centers. So we took less reduction in centers than some of the other institutes.

We did take a very serious reduction in contracts. And this was for test development methodology for new, better, less expensive tests. We

think this can be postponed at less hazard than diminishing support for investigator-initiated research.

We have no clinical trials so that was no problem for us.

By maintaining about 5,000 new grants a year, stability is created that overcomes the roller-coaster effect in available grant support.

The academic investigators are really the engine that drives biomedical research. And if we can provide for them a stable source of funding through adequate numbers of new and competing grants, we can assure them and their graduate students that money to exploit their own fresh, new, exciting ideas, will be available.

I hope I have covered your questions. Thank you, Mr. Chairman.

TOXIC WASTES

Senator WEICKER. When staff wrote the following question, they said, "We have known for quite some time that we have a toxic waste problem in this country." And that probably is the understatement of the year.

I think it would be very helpful to have your assessment of where we stand in the effort to deal with the problem. I know in my conversations with persons from industry, there tends to be the appropriate concerns expressed about nuclear waste, nuclear problems, et cetera, but it seems to me the toxic waste problem is probably far more prevalent.

We have certainly not arrived at any satisfactory solution. Indeed, every time you pick up the paper, there seems to be another problem that relates to toxic wastes. There is, I suppose, the comparison with the military side of the budget. We tend to spend so much time on strategic arms and forget about the ongoing commitments in terms of regular warfare.

It almost seems the same with regard to the toxic/nuclear situation. The nuclear is spectacular, but it is the toxic that is the one that we do deal with and are in the midst of, and obviously has a very, very adverse impact on the health of this Nation.

So I really would like to have your assessment of this whole problem. I realize you probably can talk for several hours on the subject, but try to sum it up if you can as to where we stand and whether or not adequate resources are being put into defining the solutions to the problems.

I was surprised, for example, when I read the New York Times investigative report on our corporations and waste management, which is generally considered to be the most sophisicated in the field. As I read the report, I didn't really think there was anything very sophisticated about what they were doing.

And I don't mean to get into whether they were illegal or legal; that is not the point. The point is what they were doing certainly didn't seem to me to be of a scientific level that I would require if I was saying that a company was in the forefront of its field in terms of handling this particular problem.

That is what surprised me about the article more than the legality or illegalities of it.

So where do we stand? Where are we in terms of scientific knowledge in dealing with this everyday problem? And are we adequately funding the research that has to go into it? I would like to get an opinion.

Dr. RALL. I think you have summarized the extent of the problem very well indeed. It is one of the most difficult problems to understand and comprehend scientifically.

Let me go back. About 3,000 pounds of potentially toxic chemical waste is created each year for everyone of us in the United States. It is sort of frightening to think of that number. And that has to be disposed of some way.

Now, a number of things are happening. And I think in many ways, industry has been very cooperative about this. They have learned, particularly since the oil embargo in the early seventies, that recycling really pays off, or at least it comes close enough to paying off that it is cheaper to recycle and dispose of less material than just dispose of all of it. So that is going to help us.

Second, I think the answers in terms of disposal are really not all that complex. You do not put a chemical waste dump in porous ground over important aquifers. That guarantees you enormous problems in the out-years, as they say in Washington. And that has been one of the most serious problems—digging a pit, paying no attention to its geological location, dumping everything, and then covering it with a little dirt. That is the worst kind of disposal there is.

If you find an area that is geologically stable, has impermeable layers underneath it, then dig your pit. Put some clay in the bottom to insure that it really is watertight, line the sides with clay, put all your material in there, put a clay cap on, put some dirt on that, and plant grass. You have got what is really an adequate disposal system. It is really very simple; but that has rarely been done. I think more and more, it is being done. I sound like an engineer; but I am not.

In terms of the sort of hazards we will see, I don't think we are going to see Love Canals happening very often. Very rarely, fortunately, did city planners or building developers build houses adjacent to a known toxic chemical dump. It has happened a few places; we will undoubtedly learn that it happened in a few more.

The problem I see is what I referred to earlier, putting the toxic chemical pit on top of an aquifer. About half of our public drinking water comes from underground water aquifers which we drill to get the water, generally viewed as pure.

In fact, increasing numbers of cities have found that the water that they get from drilling, particularly in Long Island, for instance, is highly contaminated by chemicals from some dump somewhere upstream of the aquifer. This is going to pose the major problem.

We have identified about 10 percent of the chemicals contaminating these aquifers. We don't know what 90 percent are. Many of the 10 per-

cent are solvents which can do a lot of things. One of the things they can do is cause kidney disease.

We have a study looking at end-stage renal disease to see whether there is any relationship to exposure to such solvents. And we think this could be very useful when particularly our Nation spends $1.5 billion a year on end-stage kidney dialysis.

We are trying to study intensively the toxicology of compounds found in ground water. We are working closely with the people in the EPA's superfund program who in fact will probably help provide funding for some of our studies in the toxicity of trichloroethylene and similar compounds.

One area about which we feel scientifically very uncomfortable with is what we call combination toxicity. We may know the toxicity of three individual compounds, for example, but what happens when you are exposed to all three at once? We don't have much of a grasp on that. We have a couple of scientific meetings devoted to this problem coming up in the future.

We put out a request for applications for grants to try to get the best advice we can from the scientific communities on how to test for combination toxicity.

Where are we in relation to the problem of waste dumps? We are better off, much better off, than we were before superfund was passed. Before superfund, we had absolutely no way of approaching these problems.

Now, we have a system to approach the problems, working through the Public Health Service and through the Environmental Protection Agency. There are now mechanisms to investigate such dumps and to provide funding for the investigation in a very timely manner which we didn't have before; and there are mechanisms to clean up the dumps.

It is going to be a mess. What I am saying is we are better off than we were, but we have got a long way to go.

That is a long answer.

MARINE SCIENCE

Senator WEICKER. No; it is a good answer.

One issue of concern to me is that about 5 years ago, I became deeply involved in marine science, which is sort of my specialty, both within and outside of the Senate. And more and more, as people have waste problems, I hear them say, "Dump it in the ocean, take your boat and burn it, go out in the ocean and start burning it out there, or dump it out there."

I don't mind telling you that you know as well as I do in the basic sense—and I am a layman, and this is maybe not your oar either—but it is a very fragile environment out there and probably represents the last greatest resource of which we have almost no intimate knowledge.

Does the work that you do also involve what the consequences are going to be with any sort of an indiscriminate policy of getting rid of the problem in the ocean?

Dr. RALL. Yes; we have a small marine and fresh water biomedical research center program.

Senator WEICKER. Do you coordinate with NOAA at all?

Dr. RALL. We share information regarding our mutual activities in ocean pollution research. They tend to be more interested in physical characteristics, but we are very concerned about the close in-shore waters, problems of heavy metals. For instance, the problems of some of the rivers in your area where there is a fair amount of cadmium, zinc, and lead.

There are interesting problems in oysters in some of those areas. And we are looking into that. They may, for one thing, provide interesting models for human disease, but they directly potentially contaminate an important part of the food supply. And this, I think, is extremely important.

PREPARED STATEMENT AND SUBMITTED QUESTIONS

Senator WEICKER. Dr. Rall, thank you very much.

There will be other questions for response to the record. Thank you.

I look forward to visiting down in North Carolina. Where in North Carolina are you located?

Dr. RALL. In the Research Triangle Park, which is between Raleigh, Durham, and Chapel Hill. We would be delighted to see you.

[The information follows:]

STATEMENT OF DR. DAVID P. RALL

Mr. Chairman and Members of the Committee, I am pleased to be with you today to tell you about some of the important research projects being supported by or conducted at the National Institute of Environmental Health Sciences.

NIEHS was established in 1966 to provide a center within the Federal Government to conduct biomedical research on the effects of environmental agents on human health. The Institute's creation was a response to two trends which emerged in the late 1960s.

First, the Nation's critical health needs had shifted. We were once most concerned about acute communicable diseases such as pneumonia, tuberculosis and influenza--diseases caused by infectious agents, identified by medical research, and brought under control. Now we were becoming more concerned about chronic problems such as cancer, heart disease, and birth defects--diseases of largely unknown origin.

Second, the rapid introduction in the post-World War II period of vast numbers and amounts of synthetic organic chemicals--substances not found in nature--was having an observable effect on our environment and on some species, such as birds and fish.

Thus, NIEHS was created to use the tools of science to investigate the effects of agents in the environment on human health through a carefully structured research program within the National Institutes of Health. The ultimate aim of this research is to develop the knowledge needed to prevent environmentally-caused effects such as kidney and pulmonary disorders, cancer, birth defects and immune system disorders.

At NIEHS we bring together scientists from many related fields to conduct both basic research--that is, research aimed at developing a fundamental understanding of biological systems or mechanisms--and applied research--that is, research which looks at particular endpoints or tries to solve particular problems. This research at NIEHS is conducted through four Programs: the Biometry and Risk Assessment Program (BRAP), the Extramural Program (EP), the Intramural Research Program (IRP), and the Toxicology Research and Testing Program (TRTP). I would like to tell the Committee about some of the completed, ongoing, and planned research in each of our Programs.

Last year, I informed this Committee about our work in genetics. This is a rapidly expanding area of basic research, an area which has been surging ahead in the last decade because newly-developed tools for recombinant DNA studies, gene cloning, and DNA sequencing allow us to manipulate genetic material directly. Researchers in the NIEHS genetics laboratory studying the structure of DNA and the functioning of genes are increasing our understanding of how the genetic code operates and how damage from chemicals or other physical agents can cause cancer, birth defects, or other harm to our health or to that of our children.

Recently, researchers discovered that at the so-called "hot spots"--areas on the DNA where there is a naturally high rate of

mutations, or changes in the location of specific genes--there are short unpaired nucleotides which loop out of the DNA's helix. This newly-discovered structure is common to several of the lower species and our geneticists are now looking at mammalian cell DNA to see if the structure is present there as well. Understanding more about the mechanism of chemical mutations--the hows, wheres, and whys--will help us develop better methods to detect mutations and understand their effect on our health.

Much of the research we support through grants or contracts attempts to characterize the health hazards to which people are exposed. One basic research project is concerned with air pollution. Our Environmental Health Science Center at The Massachusetts Institute of Technology looked at the combustion effects of burning coal to make electricity, an increasing power source as a result of the world-wide shift in energy costs.

When coal is burned, most of the by-product of the burning process becomes bound in large pieces of ash which are caught by pollution control equipment. However, some minerals escape and form tiny particles which take refuge in our lungs. Scientists found that when the combustion takes place under conditions of high humidity, two pollutants--sulfur dioxide and zinc oxide--combine to form aerosol by-products that are even more toxic than either of these is separately. When inhaled by laboratory animals these particles--which are coated with sulfuric acid, sulfates, or sulfites--cause the lungs to restrict the amount of oxygen absorbed in the blood. The discovery of this new chemical reaction during coal-burning could lead to modification of existing power plant design that will better protect human health.

We are also supporting work that studies the air we breathe indoors, where we spend most of our time. As the prices of heating oil and natural gas have risen dramatically over the past decade, Americans have tried to save money by more effectively insulating their homes to conserve energy. They have also been turning to alternative, less-expensive sources of heat such as wood stoves and kerosene heaters. Because adding insulation not only lowers residential heating costs, but also traps the air in their homes, it is important to look at the effect of emissions from these alternative sources of heat on indoor air quality.

Science magazine in December reported results from a study by NIEHS supported researchers at the Yale School of Public Health. The Yale scientists looked at what happens to the air quality when several brands of unvented portable table kerosene heaters are tested under various carefully controlled conditions.

The Yale team discovered that under certain conditions--including poor ventilation--these kerosene heaters can create indoor levels of toxic air pollutants--nitrogen oxide, sulfur dioxide, carbon monoxide, and carbon dioxide--which exceed ambient air quality standards set for outdoors under the Clean Air Act and even, in some cases, the standards set by the Occupational Safety and Health Administration for workplace exposures. Thus, as with so many environmental problems, we need to be sure that in our efforts to conserve energy, we do not inadvertently create future health problems.

In the 1960s there was a popular saying, "You are what you eat." In a scientific sense this is true. During our lifetimes we consume vast amounts of food to replace what our body uses up. In fact, by the time we are 50, we have consumed 30-50,000 pounds of solid food and thousands of gallons of liquids. This underscores in a very dramatic way the fact that in the process of eating, we provide a major route for possibly toxic chemicals to enter our bodies.

I want to emphasize that the food we eat is much safer today than in the days before refrigeration and other food preservation techniques controlled our consumption of harmful organisms. To a great degree our increased health and longevity in this century is due to our having better food, water, and sanitation. But it is also true that we know very little about the toxicity of many of the components of our diet and less about what happens to these components when we digest them.

Under an interagency agreement with the Department of Energy's Lawrence Livermore National Laboratory, we are conducting basic research to help us understand the toxicity of various foods. These researchers have been using short-term tests to determine how cooking various types of foods produces mutagens--that is, substances which may be precursors to cancer.

The investigators have found that mutagen formation when cooking protein-rich foods depends upon three factors: food type, cooking temperature, and cooking time. They have also found that many foods common to the American diet--which consist to a large degree of protein-rich foods such as beef, pork and veal--are highly mutagenic when they are cooked well-done on a griddle or in a broiler. Other sources of protein less common to our diet--but more common in those of other countries--such as tofu (bean curd), cheese, milk, and some fish, do not produce nearly as many mutagens.

As our knowledge of the relationship between mutagenesis and carcinogenesis increases, and as we combine this information with what we know about the correlation of rates of different types of cancers and different diets around the world, our increased understanding of food chemistry may be useful in developing diets that will lower our risk from some cancers.

A large part of the NIEHS' effort in applied toxicology research is conducted by the Toxicology Research and Testing Program, a major part of the Department's National Toxicology Program (NTP). The NTP has two related jobs: it tests chemicals of public health and scientific concern to determine if they cause toxic effects and it also represents the leading effort in the world aimed at developing newer, faster, and less expensive methods to determine whether chemicals may be hazardous.

A major portion of the NTP effort now involves conducting long-term toxicity studies using rodents. These studies are the best available tool medical science has for determining whether chemicals may cause cancer in humans.

Significant improvements are being made in this testing program. Whereas this Program was formerly designed to determine whether chemicals can cause cancer in animals, the NTP is

broadening the Program to provide truly comprehensive toxicological profiles of the chemicals tested.

Consistent with the NTP's mandate, the dose-range experiments that precede two-year cancer studies will also better detect and define a wide range of toxicities, such as injury to the liver, lungs, and kidneys. Studies are now routinely performed to help us understand the absorption, distribution, and excretion of chemicals at various concentrations. The NTP also conducts several types of short-term tests to determine the test chemical's potential to affect the gene components of cells. These data will help us make more informed decisions about priorities for proceeding with the two-year cancer and chronic study.

The long-term studies have been improved by the addition of an extra dose level and an interim evaluation group. This helps assure that the resulting data from these studies is more meaningful for assessing the hazard potential of chemicals found to be associated with cancer.

We are also scrutinizing traditional testing practices to see if we can realize cost savings without detracting from the quality of the studies. The net effect of these changes to date is to test fewer chemicals yet test them more thoroughly. These changes are essential if we are to develop a capability to effectively assess risk and regulate appropriately once a hazard has been detected.

Last year when I testified before you, I reported on our study of approximately 800 mothers and their children. We are looking at possible relationships between chemical contaminants such as PCBs and DDE, a metabolite of DDT, in the milk of nursing mothers and the health of the mothers and their children. I am pleased to report that so far the mothers and the children are doing fine. We have made an interesting observation: women with higher levels of DDE--even though they are unaware of these levels--tend to stop breast feeding sooner than those with lower levels, a possible indication of a dose-response relationship. We are not sure why this is so.

Some of the mothers participating in this study had been accidentally exposed to PCBs illegally dumped on North Carolina roads. While the overall level of PCBs found in their milk was not different from what is normally found, the particular type of PCBs dumped was sufficiently different from one background that we were able to document that a small amount of chemical had likely been absorbed from the spill. This illustrates the problems of investigating environmental exposures to complex mixtures when background levels are present. Levels of chemicals, however exotic, are not interpret-able without simultaneous control data. Conversely, levels of a class of chemicals in exposed groups that are similar to controls are not absolute evidence that special exposure has not taken place. Since exposure to a wide variety of environmental chemicals is the rule, considerable ingenuity is required of investigators attempting to link exposures with disease.

This Committee directed us to conduct studies to determine whether there are health risks associated with ingested asbestos, the type of exposure you might get by drinking water that passed through asbestos pipe or which came from a supply that is con-

taminated. It is well established that when inhaled, asbestos can be extremely hazardous, causing asbestosis, mesothelioma, lung and other cancers. To date, the NTP Peer Review Committee has looked at four of seven studies underway--two involving amosite, one involving crysotile, and one involving tremolite. All four studies indicate that there is no health risk to people who inadvertently drink water containing small amounts of asbestos. I will continue to keep this Committee informed of these results.

Our budget request for Fiscal Year 1984 is $165,884,000, which represents an increase of $1,517,000 over the comparable 1983 level. I would be happy to answer your questions.

Biography of Dr. David P. Rall

Birthplace and Date:	Aurora, Illinois; August 3, 1926
Marital Status:	Married; two children
Education:	Public Schools, Naperville, Illinois B.S., North Central College, Naperville (1946) M.S. (Pharmacology), Northwestern University (1948) Ph.D. (Pharmacology), Northwestern University (1951) M.D., Northwestern University School of Medicine (1951)
Professional Training:	Internship; Second (Cornell) Medical Division, Bellevue Hospital, 1952-53
Experience:	Director, National Institute of Environmental Health Sciences, NIH, 1971-present Director, National Toxicology Program, 1978-present Assistant Surgeon General, USPHS, 1971-present Associate Scientific Director for Experimental Therapeutics, National Cancer Institute, 1966-71 Medical Director, USPHS, 1963-71 Chief, Laboratory of Chemical Pharmacology, National Cancer Institute, 1963-69 Senior Surgeon, USPHS, 1959-69 Head, Clinical Pharmacology and Experimental Therapeutics Service, General Medicine Branch, National Cancer Institute, 1958-63 Surgeon, USPHS, 1955-59 Scientist, Laboratory of Chemical Pharmacology, National Cancer Institute, 1953-55 Research Associate in Pharmacology, Northwestern University, 1950 Assistant in Pharmacology, Northwestern University, 1949-50 Baxter Fellow in Pharmacology, Northwestern University, 1947-49

Association Memberships:

American Association for the Advancement of Science
American Association for Cancer Research
American College of Preventive Medicine
American Public Health Association
American Society for Clinical Investigation
American Society for Pharmacology and Experimental Therapeutics
Federation of American Societies for Experimental Biology
Society for Occupational and Environmental Health
Society for Risk Analysis
Society of Toxicology

Honors and Other Special Scientific Recognition:

Arnold J. Lehman Award, Society of Toxicology, March 1983
Editorial Board, Regulatory Toxicology and Pharmacology, 1981-present
Editorial Board, Risk Analysis, 1981-present
Head, DHHS Delegation, US/Japan Non-Energy R&D Cooperative Agreement Joint Committee Meeting, Tokyo, Japan, September 1981
Chairman, WHO Programme Advisory Committee, 1980-81
Member, WHO Programme Advisory Committee, 1980-present
Editorial Board, American Journal of Industrial Medicine, 1980-present
Member, Institute of Medicine, National Academy of Sciences, 1979-present
Nellie Fox Lecturer, Northwestern University Medical School, April 1978
Chairman, Committee on Health and Environmental Effects of Increased Coal Utilization, 1977-78
Harrington Lecturer, University of Buffalo, April 1976
Member, NAS Safe Drinking Water Committee, 1975-1977
Member, DHEW Secretary's Review Panel on New Drug Regulation, 1975-76
Associate Editor, Journal of Toxicology and Environmental Health, 1974-78
Editorial Board, Archives of Environmental Health, 1973-76
Chairman, DHHS Committee to Coordinate Environmental and Related Programs, 1973-present
Chairman, Subcommittee on Environmental and Occupational Health, Joint Working Group on Health Cooperation, US/Egypt Cooperative Agreement, 1972-present
US Coordinator, Environmental Health Program, US-USSR Health Exchange Agreement, 1972-present

US Coordinator, Biological and Genetic Consequences Project, US-USSR Environmental Protection Agreement, 1972-present
US Coordinator, US-UK Cooperative Program in Environmental Health Sciences, 1972
Adjunct Professor, University of North Carolina, Chapel Hill, 1972-present
Chairman, OST-CEQ Ad Hoc Committee on Environmental Health Research, 1971-72
Associate Editor, Cancer Research, 1970-74
Chairman, DHEW Departmental Committee on Drug Research and Regulations, 1970
Editorial Board, Pharmacological Reviews, 1969-72
Chairman, National Institute of General Medical Science Pharmacology-Toxicology Review Committee, 1967-69
Member, National Institutes of Health Chemotherapy Study Section, 1965-67
Editorial Board, Proceedings of the Society for Experimental Biology and Medicine, 1962-65
Lecturer in Physiology, Medical School, George Washington University, 1958-62
PHS Meritorious Service Medal, 1966
DHEW Distinguished Service Medal, 1975

Research Interests: Dr. Rall has authored and co-authored approximately 150 published papers relating to comparative pharmacology, cancer chemotherapy, blood-brain barrier, blood CSF barrier, pesticide toxicology, and drug research and regulation.

Questions Submitted by the Subcommittee

POOR AIR QUALITY

Question: You state that a study of people in six cities by the Harvard School of Public Health found that children living in cities with poorer air quality "tend to have more respiratory disease." Is this a new development -- or is it just more confirming evidence of the problem?

Answer: The concept of an association of respiratory illness and poor air quality is of course, not new, however, the Harvard Six City Study in comparing cities with varying air quality with respiratory illness in children over a prolonged period of time is providing the most comprehensive and reliable data yet produced. Early analyses of the data suggest that respirable particle concentration and respirable sulfate concentration are highly correlated with respiratory health indices across cities. Cross sectional analysis of respiratory symptoms identified a strong association between outdoor concentrations of mass respirable particles or sulphur dioxides and history of bronchitis, respiratory illness and cough. Also, noted were unexplained variations in illness and

symptom rates among cities which implies large uncertainties in generalizing the results to other communities at this time.

Question: The Harvard Study said that indoor air quality is also a major factor in susceptibility to respiratory disorders. Is controlling air pollution the main problem here, or do you see additional approaches?

Answer: The association of indoor air quality with respiratory illness took into consideration ambient air quality (outside air entering) and contributions to air quality from gas heating and cooking and the presence of smokers in the household. It was thought that the association between passive smoking and the incidence of illness, and between reduced lung function in children in gas cooking homes could be substantial, however, the health significance of these exposures and the dose response relationship associated with respiratory health effects remain to be determined.

The findings suggest that control of air pollution could have a meaningful effect on respiratory illness regardless of the source.

CHEMICAL HAZARDS

Question: There are more than 43,000 chemicals in commercial use. To maximize public health protection, it's critically important to have a scientifically sound selection procedure to identify and rank potentially hazardous chemicals. How do you select the chemicals to be examined for their possible effects on human health -- and where within your Institute is the selection made?

Answer: To begin with, member agencies of the National Toxicology Program and other sources (other Federal agencies, state agencies, the public, labor, and industry) submit nominations of chemicals for various types of toxicological testing. NTP staff have also begun to submit nominations of chemicals for additional toxicological studies on the basis of results from NTP studies of other toxic end-points of these chemicals.

All nominated chemicals are first reviewed to determine which chemicals have been tested, are already on test or scheduled for test, or have been previously considered and rejected for testing by NTP or its predecessors. Literature searches are performed. Relative data generated therefrom are assessed.

An executive summary is prepared for each nominated chemical. These documents contain summary information regarding known toxicological affects of the nominated chemicals and structurally related compounds, as well as data on production, use and exposure which are important in evaluating the toxic properties of the chemical.

The executive summaries on a group of nominated chemicals are sent to the NTP Chemical Evaluation Committee (CEC), composed of representatives from the Consumer Product Safety Commission (CPSC), Environmental Protection Agency (EPA), Food and Drug Administration (FDA), Occupational Safety and Health Administration (OSHA), National Cancer Institute (NCI), National Institute of Environmental Health Sciences (NIEHS), National Institute for Occupational Safety and Health (NIOSH), National Center for Toxicological Research (NCTR), and National Toxicology Program (NTP). The CEC then meets

and evaluates the nominated chemicals, recommending the types of testing to be performed and assigning priorities for such testing.

A Federal Register notice is then published which lists the chemicals reviewed by the CEC and the recommended types of testing. Also, the notice solicits comments from interested parties as well as information on completed, ongoing, and planned testing in the private sector. The list of chemicals is also published in the NTP Technical Bulletin along with a request for comments.

Revised executive summaries which contain the CEC recommendations and public comments on the nominated chemicals are then forwarded to the NTP Board of Scientific Counselors for review. The Board subsequently meets to evaluate these data and to make testing recommendations based on the available information.

The NTP Executive Committee, which consists of the heads of the participating regulatory and research agencies, then reviews all of the materials on the nominated chemicals and decides whether to test, defer, or delete each of the chemicals for the various types of testing. The Committee also sets priorities for the testing of selected chemicals.

Question: Does the group selecting the chemicals to be examined include physicians, toxicologists, and environmental health scientists, as well as lawyers and policy experts?

Answer: The NTP Executive Committee, which consists of the heads of the research and regulatory agencies participating in the Program, makes the ultimate decisions on which nominated chemicals will be selected for testing and which will be rejected. A number of the members are physicians, toxicologists and/or environmental scientists while others are lawyers and policy experts. In making their decisions, the members utilize testing recommendations developed by two panels of health scientists, one Federal and one non-governmental, as well as input received from the public.

Question: When chemicals are recommended by other Federal agencies to NIEHS for examination, what is the procedure by which you decide whether or not to examine them?

Answer: When other Federal agencies submit nominations of chemicals to the NTP, they are referred to the NTP chemical selection coordinator for review and are given the same level of consideration that nominations from NTP member agencies are given.

CADMIUM AND IMMUNE FUNCTION/SMOKING

Question: You say your studies show that "at lower exposure levels (the metal) cadmium appears to enhance immune function, but as levels increase, immune functions appear to be suppressed." That's a somewhat intriguing statement. What does it mean -- and what significance does it hold for organ transplants and other medical activities where the immune system is a major factor?

Answer: The result of the cadmium study on the immune system may be a new problem in immunotoxicology and it is important in that there is a need to identify those chemicals in the environ-

ment that influence the function of the immune system. Cadmium is ubiquitous in the environment and is accumulated by everyone during his/her lifetime.

The impact of this effect of cadmium on persons with excess exposure is unknown, but it is most probably too subtle an effect to have significance for recipients of organ transplants. However, it may have significance for immune disorders of unknown cause, such as the Acquired Immune Augmentation Syndrome (non-clinical defect of white blood cell function) or Acquired Immune Deficiency Syndrome (AIDS).

Question: You also say that according to a study, high levels of exposure to sulphur dioxide, particulates and hydrocarbons are "more significant" in the development of respiratory impairment than whether one smokes cigarettes or not. Do you apply this to lung cancer -- and are you suggesting that cigarette smoking is not all that harmful?

Answer: The epidemiologic study referred to related chronic obstructive respiratory disease (CORD) and functional respiratory impairment with long-term exposure to photochemical oxidants. The results suggest that both active smokers and people who have never smoked residing in an area exposed to high levels of photochemical oxidants have poorer lung function than residents exposed to low levels of these pollutants.

Although smoking is known to affect primarily small airways in the lung, the tests in which the greatest differences between the two areas were observed were those which incorporated function of large airways. It is possible that the site(s) of damage due to smoking or air pollutant exposures may differ.

The findings do not imply that smoking is not an important contributor to respiratory disease, but only speaks to the role of air pollutants (photochemical oxidants, sulfates, nitrogen oxides, and particulates) as possible additive factors.

LEVEL WORKFORCE

Question: Your staff positions have remained constant at 620 since 1982 and are projected to be at the same level in FY 1984. However, your funding level will increase by about $13 million over the same period. How can you do more -- and spend more -- with no increase in staff over the three year period?

Answer: NIEHS received position increases in the 1980 and 1981 budgets in order to properly operate our new facilities and staff research support functions. NIEHS also received 31 positions in 1982 to expand selected research programs. Because of successive hiring limitations and delays in completion of our facilities, we have not yet filled all vacant positions. We expect to have positions filled by FY 1984. Increases in in-house operations over this same period have been related to the costs of operating additional research facilities and properly equipping new laboratories.

Question: Can we assume that the level staffing you project means that no reductions in force are contemplated in the coming fiscal year?

Answer: We do not contemplate reductions-in-force in 1984.

PROTECTING THE INVESTMENT

Question: At a time when many budgets are going down, Congress has been increasing funding of the National Institutes of Health, including your Institute. We are concerned that these scarce resources be carefully and effectively used and that there be no basis for criticism of your management of this money. What assurances can you give that your Institute is making careful and effective use of the appropriations we provide for you?

Answer: The best assurance of careful and effective use of funds for research is careful and continual review of research emphases and fine tuning of these emphases in response to new data on needs and scientific discoveries.

For the long term, NIEHS has been through two reviews of research needs by groups of expert leaders in the field of science relevant to environmental health. Task forces in 1970 and 1976 have provided blueprints for long-term growth and development; deliberations and findings are open and subject to review and comment from the scientific community. A third task force is now being organized in response to Congressional mandate.

On a short-term basis, the program reviews and deliberations of advisory committees provide advice and guidance to the Director and the program managers. The National Advisory Environmental Health Sciences Council reviews overall direction and balance of the investigator initiated research programs. The National Toxicology Program Board of Scientific Counselors provide the same function for Toxicology Research and Testing efforts. The Intramural Research Program (IRP) Board of Scientific Counselors intensively reviews in-house basic research and make specific recommendations for improvement. The IRP Board reviews each research program at least once every three years.

The key features of these mechanisms are the participation of expert scientists from outside the Government and their discussion and advice on program activities.

Question: Aside from the peer review system, what institutional arrangements do you have that serve to deter waste, fraud, or abuse in the handling of Federal funds?

Answer: There exist agency-wide management control systems which combine the review and approval mechanisms by management experts; such as financial managers, procurement officers, grants management officers, and other administrative management specialists; with the review and approval by program managers responsible for the conduct and completion of program responsibilities. This partnership assures the balance of program objectives with the objective of adhering to legal and regulatory requirements.

The major expenditure of NIH and NIEHS funds is for Extramural Research support. The principle of dual review by non-Government reviewers is a major means to deter waste, fraud, and abuse in research activity. This peer review when coupled with the activity of professional management specialists in grants management and contracting, assures the conduct of these programs in a scientifically valid and legally proper manner.

A final mechanism to deter improprieties is the effective utilization of supervision and performance management systems provided by the Senior Executive Service and the Merit Pay performance planning and management systems. This allows program managers to assess the performance of their subordinate managers, and supervisors with regard to the proper use and control of resources for which they are responsible. This system when properly applied, helps to deter the improper utilization of these funds and other resources.

TOXIC WASTES

Question: We've known for quite some time that we have a toxic waste problem in this country. The turmoil at the Environmental Protection Agency has served to heighten this awareness. How would you characterize the nation's efforts to deal with toxic waste dumps -- and what recommendations have you been making about this aspect of the problem?

Answer: By way of background, I believe that toxic chemical waste dumps pose some of the most perplexing environmental health problems we have had to face in terms of prevention, control, and understanding of the underlying scientific issues. In addition, because of its breadth and complexity, implementing the Comprehensive Environmental Response Compensation, and Liability Act of 1980 (CERCLA) has presented major problems. I am hopeful that the coming months and years will see effective implementation of this legislation. One thing I am very positive about is that as a Nation we seem to be shortening the lag time between emergence of major environmental health issues, understanding of the issues, and development of legislation which provides the program tools to come to grips with them. In the case of toxic chemical waste dumps, much less time elapsed between identification of the issue and enactment of CERCLA. In summary, we believe there is a broad consensus that we need to take appropriate action. The National Toxicology Program (NTP) is participating in carrying out DHHS responsibilities under the Act. Our means of communicating the results of our research to others are discussed below.

Question: Your justification says: "...Prudent application of much of (the Institute's) research can lower the rates of diseases such as cancer, sterility, birth defects, and neurological disorders." To what extent is the Environmental Protection Agency aware of your research -- and to what extent does the agency use it?

Answer: There are three principal means through which NIEHS insures the Environmental Protection Agency is kept informed of its research.

1. EPA sits as a member of the National Toxicology Program (NTP) Executive Committee, which serves as NTP's major advisory group. Through this means, EPA participates in discussions of science policy issues and in timely information exchange among the various member agencies as well as with industry and other interested groups.

2. EPA is a liaison member of the DHHS Committee to Coordinate Environmental and Related Programs (CCERP), which is a multiagency group designed to provide the medium for exchange of information on environmental health and toxicology and related programs. Through its participation, EPA is kept informed of PHS research information and takes part in the design of approaches to specific environmental health problems.

3. EPA is an ex officio member of NIEHS' National Advisory Environmental Health Sciences Council (NAEHSC), which advises NIEHS concerning matters relating to programs and activities in the area of environmental health sciences, reviews applications for grants-in-aid for research projects and grants and awards for research and training activities in the environmental health sciences, and recommends approval of projects of research and training activities that merit support. By this means, EPA is kept up-to-date on progress of and plans for NIEHS-supported research.

In addition to these formal means of keeping EPA informed of NIEHS research, there are scientist-to-scientist interactions, participation of EPA scientists in NIEHS sponsored conferences on emerging environmental health problems, and distribution of timely information (such as the Institute's journal, NTP toxicology and chronic carcinogenesis testing reports, and the NTP Annual Plan) to the agency. Information on NIEHS research and its results is supplied to EPA to form part of the science base upon which the agency must construct its regulatory decisions.

For example, on April 21 EPA announced that it was undertaking an accelerated review of 4-4 methylenedianiline (MDA) under the provisions of the Toxic Substances Control Act. The basis for EPA's decision to undertake this review was a National Toxicology Program carcinogenesis study and a National Institute for Occupational Safety and Health study on worker exposure.

Question: Were there ever instances where you made recommendations to EPA based on your research -- research, for example, on dioxins -- and the recommendations were not followed?

Answer: NIEHS has responsibility for providing the scientific information it develops to agencies such as the Environmental Protection Agency so that they can make better informed decisions. In this process, the Institute provides information on its research and their results, but NIEHS, as a research agency, generally does not attempt to formulate recommendations for EPA's actions. At times, the Public Health Service may be called upon to review, from a scientific perspective, the science information upon which the EPA may be basing its proposed actions. In such cases, NIEHS may be called upon to evaluate the science, but not to recommend particular regulatory actions.

ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

Queston: We understand that you have been active in the battle against Acquired Immune Deficiency Syndrome (AIDS). To what extent is this syndrome an environmental problem, if at all?

Answer: The vast majority of current evidence appears to support an infectious etiology for Acquired Immune Deficiency Syndrome (AIDS). If this evidence is correct, AIDS does not constitute a chemically related environmental problem. However, predisposing agents or factors appear to be associated with the occurrence of the disease in specific populations, a possible relationship between potential risk and exposure to a specific chemical cannot be dismissed. It has been suggested that one such chemical that may act as a predisposing agent in homosexuals is amyl nitrite (e.g. Goedert, et al., "Amyl nitrate may alter T lymphocytes in homosexual men", Lancet, Feb. 20, 1982).

Question: What specific role has been assigned your Institute in this matter -- and how much will you spend on it in FY 1984?

Answer: NIEHS has not been assigned a specific role in AIDS related research although there are several research efforts underway within NIEHS and the National Toxicology Program (NTP) related to AIDS or possible AIDS predisposing agents.

1) Environmental Health Sciences Center Grants at New York University and Mt. Sinai Medical Center are being used, in part, as core support for studies in patients with AIDS. In addition, a conference was held July 13th at Mt. Sinai Medical Center in New York to explore potential causes of AIDS. Sponsors of this program included the DHHS Committee to Coordinate Environmental and Related Programs and NIEHS.

2) NIEHS/NTP is presently conducting a carcinogenicity bioassay of isobutyl nitrite by the inhalation route in rats and mice. This study will be completed in FY 1985. In addition, an extensive file is maintained on ongoing work with respect to the alkyl nitrites. NIOSH, as part of their NTP effort, is examining the effects of inhaled isobutyl nitrite on immunocompetence in mice.

3) It has been suggested that exogenous estrogen treatment may serve as a predisposing factor in AIDS. NIEHS is conducting studies on the relationship of exogenous estrogen exposure and immunosuppression in mice. These mice demonstrate many of the immunologic abnormalities associated with AIDS in humans.

There are no funds designated for support of research directly related to AIDS for FY 1984. However, the above efforts will be continued at a cost of approximately $250,000 in 1984 and the results as well as their possible relation to AIDS will be reported.

TRAINING TOXICOLOGISTS

Question: You indicate that there is a need for more trained toxicologists. What is your Institute doing to help increase the supply of trained individuals in this field?

Answer: First off, Mr. Chairman, because we are the major supporter of training in the environmental health sciences, we take our

responsibilities for training very seriously. For the coming fiscal year we have reduced our investment in training as a result of two factors: 1) the need to honor the committment to the support of 5,000 grants, and 2) our recent study of the need for toxicologists indicates that for the near term the rate of increase in supply need not be as great as previous manpower studies had indicated.

Thus, while we continue to believe the development of an adequate manpower pool is one of our central responsibilities, and we will continue to provide for increasing that pool, it will be at a lower rate than in the past several years.

Question: What impact will the budget request for training have on your efforts to train more toxicologists?

Answer: It will reduce the number of NIEHS supported trainees from 428 to 332. Approximately 65% of these are toxicologists in training.

Questions Submitted by Senator William Proxmire

BIOASSAY PROGRAM

Question: Dr. Rall, as your testimony indicates on page 5, the National Toxicology Program represents the leading effort in the world aimed at developing newer, faster and less expensive methods to determine whether chemicals may be hazardous. Can you discuss very briefly what some of those less expensive methods are? For example, an article which appeared earlier this year in the Journal of Fundamental and Applied Toxicology has raised some serious questions regarding the Bioassay Program which was transferred from the National Cancer Institute to your Institute. As you know, this program tests various compounds for their ability to cause cancer when fed over long periods of time to rodents. The author claims that the test, which was designed by the Federal government, was never validated properly and is very expensive and time-consuming. The article states--and I quote:

"The design of this bioassay appears to have been created out of the best thoughts of several committees and reflects the opinions of the committee members. It is suggested that a drastically different design is needed and that such redesigning will require proper validation."

The article goes on to state:

"As long as it is considered to be useful in detecting human carcinogens, this very expensive and time consuming procedure will continue to drain the toxicological resources of society. This report questions its usefulness and suggests that it is time to seriously consider alternatives."

The article appears to substantiate a report issued around the same time by the National Research Council of the National Academy of Sciences which concluded that such tests are not only much more expensive but require several months, and that quick, inexpensive tests are already available to identify chemicals that cause mutations. Can you comment on these findings? If not, I'll provide copies now and ask that you respond for the record.

Answer: While I recognize that your question is to identify those tests which we are developing which may be more rapid and less expensive, I think it is important in this response to note that in addition to those efforts, we are attempting to develop new test systems which we hope will have much more biological precision in helping to identify toxic chemicals and that this should be our first concern rather than how rapid or inexpensive they are.

In terms of direct response to your question: 1) we are expanding additional efforts to develop a faster and less expensive application of the Ames test; 2) we are attempting to develop a reliable and sensitive assay for neoplastic transformation in mammalian cells in culture; 3) in conjunction with mammalian cells in culture, we are attempting to improve the use of human cells in culture as indicators of toxic potential or neoplastic potential; 4) we are also attempting to use single cell systems to measure multiple genetic endpoints (e.g., multiple mutation and chromosome effects in one cell type which would reduce the manpower and cost per test chemical); and 5) we are attempting the use of short-term tests in animals in direct conjunction with the rodent carcinogenicity assays, specifically, by developing much more rapid tests for chromosome effects in mice and rats, and to develop assays which may have the capacity to measure chemicals which act as tumor promoters in the animal. We are now initiating new test development efforts to determine potential chemically-induced aneuploidy (i.e., alteration in chromosome number) and gene transposition (i.e., the movement of genes). In conjunction with the transposition studies, we are also especially interested in determining whether we can measure chemically induced effects on oncogenes.

In addition to the efforts in the genetic toxicology area, other test procedures have also been developed or are being assessed which are intended to help prioritize our testing activities, get critical toxicology data with less investment of time, and sometimes preclude the need for expensive test procedures: 1) a pre-screen for teratogenic potential will be investigated through the evaluation of two different procedures in two laboratories. If one or both of these tests perform well in this validation effort, they will help set priorities so that we use our existing capacity to do teratology studies wisely and not waste money doing work of low priority; 2) a continuous-breeding program is being evaluated under contract to provide reproductive data in laboratory animals for less than half the cost of a conventional reproduction study; 3) through a small addition to our ongoing subchronic toxicity studies, we are collecting data on the functionality of reproduction organs. These data help identify chemicals which are high priority for reproductive tests with only a small investment; and 4) chemical disposition studies can help compare the fate of chemicals following different routes of exposure and identify metabolites that are common to those of other chemicals. If a chemical is not absorbed or is metabolized to a chemical already tested, we may do testing by one route rather than multiple routes, or the data may preclude the need to do testing.

Question: Dr. Rall, in your opening statement you touched upon potential environmental health hazards that could affect the work being done by a great many Federal bureaus and agencies including the Occupational Safety and Health Administration, the National Institute for Occupational Safety and Health, the Environmental Protection Agency, the Consumer Product Safety Commission, the National Cancer

Institute and the Energy Department. What mechanism do you have in place to ensure that the work you are performing does not duplicate or cut against the work of those other entities?

Answer: NIEHS uses two principal mechanisms to ensure its research does not unnecessarily duplicate that of other agencies. The first of these is the National Toxicology Program (NTP) Executive Committee which provides primary oversight for the NTP. This Executive Committee is composed of the heads of the health research and health regulatory agencies concerned with environmental problems and it serves as NTP's major advisory group. The Committee advises me, as the NTP Director, on research and testing needs and on selecting and setting priorities for the specific chemicals to be tested. This interagency group also serves as a forum for discussion of science policy issues and provides for timely information exchange among the various agencies as well as with industry and other interested groups. One of the key tasks for the Executive Committee is to review and recommend approval of the NTP Annual Plan which arrays the resources available to the NTP and the compounds it has on test and proposes to put on test in the upcoming year. The Annual Plan is the principal instrument for describing the coordination of toxicology test development and testing among the health research and health regulatory agencies. It presents NTP's strategy for test method development and validation, and contains an annual report detailing NTP's accomplishments in the preceding year. Part II of the Annual Plan presents a review of current DHHS, DOE, and EPA research related to toxicology in order to foster greater awareness regarding toxicology research throughout government. Through this interactive and cooperative mechanism, the NTP is assured of a continuing interface with the health research and health regulatory agencies and of receiving input into critical phases of NTP operation, including oversight of program planning and balance.

The second mechanism NIEHS uses to insure coordination with other agencies is the DHHS Committee to Coordinate Environmental and Related Programs (CCERP), for which I serve as Chairman. This Committee was established by the Assistant Secretary for Health, DHHS, as a multiagency group to provide a medium to assure the exchange of information on environmental health and toxicology and related programs, to coordinate these programs, to enhance the sharing of resources, and to provide advice to the Department. The Committee coordinates its activities with other components of the Federal Government in areas of mutual interest and concern. It consists of a high-level representative and an alternate from each agency within DHHS supporting or conducting environmental health, toxicology, or related programs as well as liaison members who are high-level representatives from those agencies outside the Department that are concerned with environmental health, toxicology, or related programs. Reporting directly to the Assistant Secretary for Health, the Committee serves as the Public Health Service's principal mechanism for the exchange of information, coordination of activities, and, through its special purpose subcommittees, the design of approaches to specific health problems. The following is a list of members of the NTP Executive Committee and the DHHS Committee to Coordinate Environmental and Related Programs.

NTP EXECUTIVE COMMITTEE

Members

Administrator, Environmental Protection Agency
Assistant Secretary for Health, Department of Health and Human Services (non-voting)
Assistant Secretary of Labor for Occupational Safety and Health Administration, Department of Labor
Chairman, Consumer Product Safety Commission
Commissioner, Food and Drug Administration (Chairperson*)
Director, National Cancer Institute
Director, National Institute for Occupational Safety and Health
Director, National Institute of Environmental Health Sciences
Director, National Institutes of Health

* The Chairperson is elected by the Committee and serves a one-year term.

DHHS COMMITTEE TO COORDINATE ENVIRONMENTAL AND RELATED PROGRAMS

Members

Office of the Assistant Secretary of Health
Director, National Institutes of Health
Director, National Institute of General Medical Sciences
Director, National Cancer Institute
Director, National Institute of Environmental Health Sciences
Director, National Library of Medicine
Director, National Institute on Aging
Director, National Institute of Child Health and Human Development
Director, National Institute Heart, Lung and Blood Institute
Director, National Institute of Neurological and Communicative Disorders and Stroke
Director, National Institute of Dental Research
Director, National Eye Institute
Director, National Institute of Allergy and Infectious Diseases
Director, National Institute of Arthritis, Diabetes and Digestive and Kidney Diseases
Director, Alcohol, Drug Abuse and Mental Health Administration
Director, National Institute of Mental Health
Director, Centers for Disease Control (CDC)
Director, CDC/National Institute for Occupational Safety and Health
Director, CDC/Center for Environmental Health
Commissioner, Food and Drug Administration (FDA)
Director, FDA/National Center for Toxicological Research

Liaison Representatives

Consumer Product Safety Commission
Environmental Protection Agency
Occupational Safety and Health Administration
Council on Environmental Quality
Library of Congress
Department of Energy
National Oceanographic and Atmospheric Administration

Department of the Navy
U.S. Army Environmental Hygiene Agency
Wright Patterson Air Force Base
National Science Foundation

CANCER - GENETICS

Question: Dr. Rall, in your opening statement you refer to the study of DNA structure in your genetics laboratory. On the other hand there is a substantial amount of narrative in the National Cancer Institute's justifications about a new left-handed DNA form and the development of an immunoassay to determine binding of chemical carcinogens to DNA which will be used to analyze tissues from various occupational groups for the presence of DNA-carcinogen adducts. Would you differentiate for us the work you are doing from the work being supported under the Cancer Institute's program?

Answer: Considerable effort is going into the molecular characterization of genes. This involves the study of DNA at two levels. First is the primary nucleotide sequence determination that gives information about the structure of genes and the signals that are important in their regulation. The comparison of nucleotide sequences for normal and mutant forms of a gene provides information about how genes are affected by mutagens and how mutagenic changes influence function.

The second level involves examination of secondary structures that can form in DNA molecules. Structures such as palindromes that allow intramolecular pairing are implicated in the production of mutational hot spots in genes.

We are not involved in the study of Z-DNA, though that work may produce information that is important to understanding gene function and it certainly is related to secondary structures that can form in double helical DNA molecules. If there is indication that the Z-DNA form has unusual reactions with mutagens, our work may very well include the investigation of such forms in the future.

National Institute on Aging

STATEMENT OF DR. ROBERT L. RINGLER, ACTING DIRECTOR

ACCOMPANIED BY:

DR. JAMES B. WYNGAARDEN, DIRECTOR, NIH
DAVID CHICCHIRICHI, EXECUTIVE OFFICER, NIA
NORMAN P. MANSFIELD, DIRECTOR, DIVISION OF FINANCIAL MANAGEMENT, NIH
ANTHONY ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET, DHHS

BUDGET REQUEST

Senator Weicker. We will next hear from the National Institute on Aging which is in the forefront of research on the aging process.

The revised budget request for the Institute is $99.4 million, which is $3.7 million above the January budget and $5.4 million over the fiscal year 1983 level.

Here to testify before the subcommittee on behalf of the Institute is the Acting Director, Dr. Robert Ringler.

Dr. Ringler, we welcome you and your staff to the hearing.

Dr. Ringler. Thank you, Mr. Chairman.

I would like to begin by introducing our Executive Officer on my left, Mr. David Chicchirichi.

PRIORITY AREAS

The 20th century extension of life expectancy from approximately 48 years in 1900 to approximately 75 years today means not only that the number of older persons is increasing, but that an increasing number of individuals can look forward to living out their lives more fully. However, this trend also increases the proportion of adult life that may be spent in dealing with chronic disease, isolation, and other forms of social and economic deprivation.

Paramount questions confronting the National Institute on Aging are: How can the relatively vigorous health, effective functioning and productivity of the middle years be extended? And how can disability and dependency be avoided or postponed? With these broad questions in mind, the Institute has emphasized four areas: Understanding the processes of aging; the area of senile dementia of the Alzheimer's type, and related dementias of aging; promotion of health and effective functioning; and finally developing leadership in geriatrics and gerontology.

I would like to say just a sentence or two about each of these areas.

The Institute's efforts in the understanding of processes of aging cover the research spectrum, from studies at the basic molecular and cellular level in lower organisms to studies in population groups of human beings. An example of the latter is our own intramurally sup-

ported Baltimore longitudinal study of normal aging, which is a study of some 750 men and 350 women from each decade of adult life.

SENILE DEMENTIA

The second major area is senile dementia of the Alzheimer's type and related dementias of aging. These pose an enormous burden to the country in terms of morbidity, mortality, and cost. They are probably the most feared of all of the chronic conditions of the elderly. Dr. Thomas was quoted several times yesterday on various topics. Dr. Thomas' quote on this subject is that senility and the dementias really represent the disease of this century. Awareness of the dementias has increased dramatically in recent years, along with quite dramatic improvements in our understanding of them.

I am happy to report that during the past year, the Institute has been able to establish a clinical research program at the NIH Warren G. Magnuson Clinical Center. During the coming summer, we will be relocating the basic program in the neurosciences, which is currently located at the Gerontology Research Center in Baltimore, to the NIH Clinical Center.

I might just add parenthetically that the Aging Institute's intramural program is located in Baltimore at Baltimore city hospitals, while the other institutes are located at the NIH, as you know. The relocation of the basic neurosciences program from Baltimore to NIH and the development of a clinical program will facilitate our collaboration with the intramural programs of the other institutes, several of which have a major interest and involvement in the area of the dementias.

HEALTH AND EFFECTIVE FUNCTIONING

The third area I mentioned was the promotion of health and effective functioning. It is well known that advances in biomedical research and public health measures have contributed to the dramatic increase in life expectancies I referred to at the opening of this statement. We would like to emphasize several lines of investigation in this area, for example, the role of physical activity in the promotion of health and the prevention of premature physical disability. Other lines of research in this area include improved understanding of the role that nutrition plays in the aging processes and the diseases associated with age, and studies of factors associated with the institutionalization of the elderly. Examples here would include such things as urinary incontinence and hip fractures.

LEADERSHIP IN GERIATRICS

The last point I mentioned was the development of leadership in geriatrics and gerontology. The situation has improved somewhat in recent years. However, several studies have continued to highlight the relative lack of emphasis on geriatrics and gerontology at all levels of medical education.

The Institute has attempted to lend emphasis or priority, if you will, to the development of trained personnel in geriatrics and gerontology from its beginning, and we are continuing to do this through the support of a number of special mechanisms.

Mr. Chairman, that concludes my brief summary. I would be pleased to answer your questions.

Senator WEICKER. Please do.

Dr. RINGLER. We share the opinion expressed by all of the Directors who have testified thus far in support of investigator-initiated research. I think this is of particular importance to the Aging Institute since the Institute is new, and aging research, indeed, is a new area.

The April budget does provide funding for an additional 39 competing grants when compared to the January budget. I am also happy to say we were provided with $3.7 million of additional money to fund those grants. So almost all of the increase comes from new money provided to us. We will be negotiating noncompeting grants down by about 10 percent; competing ones down by about 10 percent also. With these changes and with the additional funds, we will fund an estimated 121 new and competing grants. The numbers are small, but it is a small Institute. As regards the question on centers, we do not have any competing centers up for funding in 1984. It is not an issue for us.

We have not deferred initiation of any clinical trials.

The Institute at this time is collaborating with the National Heart, Lung, and Blood Institute to support one clinical trial in the area of hypertension. This trial is at the pilot phase at the moment.

The roller-coaster effect that you refer to is extremely important to aging. The Institute is interested in attracting new investigation into the field of aging. This means there does need to be stability so that investigators can find a career for themselves in research in aging.

Thank you.

LEADS IN SENILE DEMENTIA

Senator WEICKER. Through your February report to the Committee on Senile Dementia of the Alzheimer's Type, you indicate a number of interesting leads, including a marked loss of nerve cells in the base of the brain, high concentrations of aluminum in affected brain cells, the possible role of slow-acting, transmissable viruses, and impaired sleep in the early stages of the disease.

Now, which of these leads is currently thought to be more important, or are they all of equal weight?

Dr. RINGLER. There are a number of leads in the area of the dementias which I can refer to and will.

I would point out that we have a full report on this which we can make available to the Congress to amplify what I am going to say.

Senator WEICKER. We have a copy; good.

Dr. RINGLER. Just to highlight the report and provide a brief response to your question I would like to say that, in my own personal opinion, the most significant observation in this area is the fact that this so-

called senile dementia of the Alzheimer's Type is a disease condition which is defined pathologically and is not an inevitable consequence of old age. That observation introduces the possibility of our eventually being able to treat the disease and at some time in the future being able to prevent it. So again, from the perspective of the elderly this is a most profound observation.

You mentioned aluminum. The observation is that in brains of Alzheimer's patients there is a high concentration of aluminum. The significance of this finding is not understood at the present time. The nature of the deficiency in Alzheimer's is quite well understood. It is a deficiency in a specific chemical, a neurotransmitter, specifically acetylcholine. The defect has been confirmed in a number of ways and at least two therapeutic approaches to managing the disease have been tested. I would point out that the therapeutic approaches are not ones which are likely to receive practical application in the near future. But they do at least indicate that it will be possible or may be possible to intervene pharmacologically in these diseases.

You mentioned slow viruses. There are several possible etiological or causative factors for the dementias. One of them would be genetic or some sort of a family relationship. If there is a genetic component to the dementias, it is not a simple one, and it is not straightforward. The observation is that the dementias do tend to aggregate in families, but I would point out that they also occur in later years. Longevity also tends to aggregate in families. So long-lived people tend to have more dementia perhaps because they live longer.

The viral etiology is one that is under active investigation and one that I think we would feel should be pursued very vigorously.

Senator WEICKER. Fine.

PREPARED STATEMENT AND SUBMITTED QUESTIONS

Dr. Ringler, I have further questions which I would pose to you for response to the record.

[The information follows:]

Statement of Dr. Robert L. Ringler

I am pleased to appear before you to present the FY 1984 budget for the National Institute on Aging and to report on recent progress in aging research.

The 20th century's triumph of extension of life expectancy means not only that the numbers of old persons are increasing, but that increasing numbers of individuals can look forward to living out their lives more fully. As life expectancy has been extended, the proportion of adult life that may be spent in retirement has also been increased, as has the proportion of adult life spent dealing with chronic disease, isolation and other forms of social and economic deprivation. Many important questions still need to be answered. Paramount is the question, how can the relatively vigorous health and effective functioning and productivity of the middle years be continued into the later years? How can disability and dependency be avoided or postponed?

These questions and others about how the elderly and their families cope with health and behavioral change have created increased demand for information about the aging processes and the aged themselves. Aging research is responding to this demand by developing the knowledge base needed for understanding the processes of aging and the impairments associated with being old. With this broad objective in mind, the National Institute on Aging has focused emphasis on four areas: (1) understanding the processes of aging, (2) senile dementia of the Alzheimer's type (SDAT) and related dementias of aging, (3) promotion of health and effective functioning, and (4) developing leadership in geriatrics and gerontology.

Understanding the Processes of Aging

A major goal of the NIA is to determine how and why individuals age, why they develop the physical and psychological changes associated with aging and why they manifest the diseases statistically associated with older age groups. Research in such areas as genetics, cell biology, immunology, endocrinology, neurobiology, biopsychosocial and population aging is providing insight into these questions and further explorations should provide more definitive answers.

As our understanding of the processes of aging increases we can identify biomarkers or indices of aging which can be used to evaluate interventions designed to slow or retard biological and psychological aging. The identification of biomarkers of aging will also facilitate further our understanding of the basic processes of aging. For example, there are studies which indicate that hip fractures may be prevented through interventions such as exercise, administration of calcium and vitamin D, or behavioral intervention. Additionally, behavioral experiments with older persons show that memory and cognitive functioning can often be maintained at earlier levels and even reaction time, traditionally viewed as biologically determined, markedly improved through training techniques. A recent NIA conference on the subject identified 24 possible biomarkers of aging which show some promise as indices of aging. The approach is still

very preliminary; however, we are hopeful that it will facilitate development of intervention strategies.

Senile Dementia of the Alzheimer's Type (SDAT) and Related Dementias of Aging

Senile dementia of the Alzheimer's type and related dementias of aging are an enormous burden to the country in terms of morbidity, mortality and cost and is probably the most feared of all the chronic conditions of the elderly. Awareness of the nature and magnitude of the dementias has increased dramatically in recent years and significant advances in understanding, treatment and possible prevention appear more promising today as compared with five years ago when there was little research activity directed towards these disorders.

Recent research findings are providing insights into the possible causes of SDAT and show promise for ameliorating these disorders. Scientists have found in senile dementia a reduction in the brain's ability to synthesize and release neurotransmittors, chemicals which enable brain cells to communicate with each other. The main source of energy for the brain is glucose, and a key enzyme involved in the breakdown of glucose to synthesize neurotransmittors appears to be defective in the brain of senile dementia patients. There also appears to be a link between formation of abnormal proteins in the brain and the level of aluminum and calcium inside the brain cell. It has been proposed that these abnormal changes may be due to the inability of brain cells to regulate calcium levels within the cell.

In FY 1982 the Institute's Laboratory of Neuroscience established a clinical research program at the Warren G. Magnuson Clinical Center at NIH, with use of a six bed patient care unit. The basic research program of the laboratory will be relocated from the Gerontology Research Center in Baltimore to the Clinical Center at NIH this coming summer. Location of the total program at NIH will greatly facilitate our overall research efforts in the areas of the dementias and neurosciences and will facilitate collaborative efforts with the intramural program of the other institutes. This laboratory will examine changes in the normal brain with age and the dementias, and such areas as cerebral metabolic changes. For example, glucose metabolism is one of three major interrelated measures of brain activity--the other two being brain blood flow and oxygen consumption. NIA investigators have found no significant age-related alterations in brain glucose metabolism. These studies suggest that the healthy aged brain is as active and efficient as the healthy young brain. Future studies will continue to build upon and analyze the results of this work, and will lay the groundwork for research on various pharmaceutical approaches in the treatment of the dementias.

Promotion of Health and Effective Functioning

Advances in biomedical research and public health measures have contributed to the changing demographics of the population. These have resulted in an increase in life expectancy from birth of about 47 years in 1900 to approximately 75 years today. Improvements in the control and management of infectious diseases, once the cause of major morbidity and mortality in all age groups, and more recently improved management of acute life-threatening events from chronic diseases, for example, heart attack, are major factors in this

increased expectancy. Just as these advances in the biomedical and behavioral sciences have contributed to the changing demographics of the population, the promotion of health and effective functioning will impact on the ability of older persons to live independently within the community in relatively good health.

Several lines of investigation are being pursued. Examples include the role of physical activity in the promotion of health and prevention of premature physical decline associated with the aging process. Nutrition research, another example, is directed toward understanding the role nutrition plays in the aging process and diseases associated with old age. The Institute is supporting a follow-up to the 1970-74 National Health and Nutrition Survey (NHANES I) which will provide information on the effects of nutrition on health status and survival for the elderly. We also need to emphasize research to improve the ability to deal with sensory and physical impairments for those who inevitably do become impaired as they become older. In the elderly, health attitudes and behaviors of the individual, of family and friends, and of professional caretakers all have a significant impact on health and effective functioning. Behavioral research is directed at identifying these causal relationships as people grow older.

Developing Leadership in Geriatrics and Gerontology

A recent survey conducted by the American Medical Association on physician preferance resulted in the finding that only 650 physicians of some 465,000 respondants expressed a preferance for geriatrics. Other studies have highlighted the relative lack of emphasis on aging at all levels of medical education. Additionally, research in geriatrics and gerontology is a relatively new area. Since its inception, the Institute has stressed the need to develop the field of geriatrics and gerontology, and has responded to these needs by supporting several special award mechanisms. These include the Geriatric Medicine and Dentistry Awards, the Academic Award, the Clinical Investigator Award, and the Teaching Nursing Home Award. We anticipate that these awards will have a substantial impact on the future development of geriatrics and gerontology.

As reported to you previously, the Teaching Nursing Home Award provides an excellent opportunity for developing geriatric research. The program was initiated in FY 1982 and currently supports two awards. Funded projects include studies on senile dementia, osteoarthritis and gait disorders, urinary tract infections, cognitive therapy for stroke rehabilitation, and sleep apnea. The NIA will continue to support this program and plans to make additional awards in 1983 and 1984.

Another opportunity for developing leadership in geriatric medicine exists at the Gerontology Research Center (GRC) in Baltimore and at the Institute's Laboratory of Neuroscience, as it becomes fully operational at the NIH Clinical Center. As you know, the Gerontology Research Center is located on the grounds of Baltimore City Hospitals, which is an affiliated hospital of the Johns Hopkins University. Over the years there have been a number of collaborative research efforts between scientists at GRC and those at the university. The medical school has recently recruited an acknowledged expert in geriatrics to expand their emphasis in the

field of aging. We are currently exploring opportunities for further collaborative efforts with them, both in the area of research geriatric medicine and in training of physicians and other scientists in geriatrics and gerontology.

Mr. Chairman, the FY 1984 budget request for the National Institute on Aging is $99,408,000.

Biography of Dr. Robert L. Ringler

Ringler, Dr. Robert L.
Acting Director, National Institute on Aging, NIH

March 27, 1922; Chase, Michigan. Married, one son.

Education. A.B. (with honors) (Chemistry and Biology), Central Michigan College, 1951. Ph.D. (Biochemistry), Michigan State University, 1955.

Professional History. 1951-1955, Graduate Assistant, Michigan State University. 1955-1957, Assistant Professor, Department of Biochemistry, North Carolina State College. 1957-1961, Senior Associate, Enzyme Division, Ford Institute for Medical Research, Henry Ford Hospital. 1961-1962, Scientist Administrator, National Heart, Lung, and Blood Institute (NHLBI), NIH. 1962-1966, Chief, Program Projects Branch, NHLBI, NIH. 1966-1967, Head, Task Force on Cardiovascular Research Centers, NHLBI, NIH. 1967-1968, Acting Chief, Program Project Branch, NHLBI, NIH. 1967-1969, Chief, Institutional Research Programs, NHLBI, NIH. 1969-1970, Acting Associate Director for Collaborative Research and Development, NHLBI, NIH. 1972-1973, Acting Director, Division of Blood Diseases and Resources, NHLBI, NIH. 1974-1975, Acting Director, NHLBI, NIH. 1969-1978, Deputy Director, NHLBI, NIH. 1978-1982, Deputy Director, National Institute on Aging (NIA), NIH. 1982, Acting Director, NIA, NIH.

Professional Organizations. Sigma Xi, American Society of Biological Chemists, American Heart Association, American College of Cardiology Fellow, Gerontological Society of America.

Honors, Awards. 75th Anniversary Award, Central Michigan University, 1967. DHEW Superior Service Honor Award, June 1970. Senior Executive Service Bonus Award, 1981.

Questions Submitted by the Subcommittee

USE OF PRESCRIPTION DRUGS

Question: People over 65 make up 11 percent of the population but use some 25 percent of all prescription drugs. Some may use a number of prescription drugs at the same time, not all from the same doctor. This could lead to prescribing errors if information about use of therapeutic drugs is not coordinated. What are you doing to alert doctors, pharmacists and especially the elderly to the importance of coordinating information about prescription drug use?

Answer: The NIA has prepared an Age Page on safe drug use by older people. Approximately one million copies were printed in late 1980, and distributed to individuals on the NIA mailing lists; to supermarkets and pharmacies for display in free literature racks; and to organizations such as departments of public health, area agencies on aging, health clinics, and other outreach centers. In 1982, this fact sheet was updated by the NIA and the FDA and an additional 100,000 copies were printed. A Spanish translation has been prepared and copies will be printed and distributed during 1983.

The NIA receives over 100,000 inquiries from the public each year, many of which request information on drug use. Every effort is made to respond fully to each request, either by providing information on drug side effects or by referring the individuals to pharmacists or medical specialists. Many health professionals and researchers also contact the Institute seeking information on current research findings in the area of pharmacology. In addition, the Institute receives numerous press inquiries concerning medication needs and problems in older persons. A newspaper article based on information supplied by the Institute has been published.

In the past several years, the Institute has prepared technical articles for publication in journals such as Drug Intelligence and Clinical Pharmacy, Psychopharmacology Bulletin, and Pharmacy Times. These articles present information on special health problems in the elderly, future research needs, and new research findings that can be applied immediately to older patients.

In early 1982, a representative of the Institute spoke before the FDA Committee on Patient Education, a group established to coordinate FDA and government-wide activities related to patient drug education and to work with the private sector in stimulating further initiatives in this area. Information was presented on the best methods of reaching older people and types of information most ofter sought by the elderly.

The NIA has proposed a collaboration between the United States Pharmacopeia, the American Association of Retired Persons, and the NIA to produce a paperback book on drug use for older consumers. Eminent pharmacologists and clinicians will be asked to provide information about specific drugs used frequently by older persons, which will be combined with information on general issues such as questions to ask physicians and pharmacists, how to keep track of multiple medications, and side effects most often seen in the elderly. The first planning meeting is scheduled for the summer of 1983.

Question: What research are you doing on age related changes in drug absorption in the elderly?

Answer: Changes in drug absorption with age has proven to be a complex issue. The absorption of some kinds of drugs is affected by age, whereas absorption of other drugs is not. Age may also affect how the body metabolizes drugs, the kind of side effects a drug may produce, and even the drug's toxicity. At the present time the NIA is funding one research grant which is examining this matter in greater depth. Once the Institute's intramural Laboratory of Neurosciences becomes fully functional at the NIH Clinical Center, it also will address this issue.

SMALL GRANTS AWARD

Question: We note that you have started your small grants program with 18 awards. What's the purpose of these awards, what is the average size of the award, and how do they differ from your traditional research grant?

Answer: The National Institute on Aging has awarded 18 small grant awards since the beginning of this program in February 1982. These awards are intended to provide support for pilot projects, testing of new techniques, or feasibility studies of innovative and high risk studies which would provide the basis for more extended research. The primary differences of the small grant from other more traditional awards is its limitation to a one year, non-renewable, $15,000 (direct cost) pilot study with quick turnaround for review and funding, usually within four months.

Question: Is there a peer review process involved in the small grants? In other words, who decides which applicant will get an award?

Answer: As with other grant mechanisms, peer review by a technical review group and the National Advisory Council on Aging determines relative scientific merit and relevance upon which funding decisions are based.

TRAINING

Question: Your January justification states that the aging research field is young and needs trained researchers. You add that your Institute places "great importance" on recruitment and training. Yet your original FY 1984 training budget requested 15 fewer new training awards -- and 15 fewer new institutional awards. The revised budget cuts training by another $55,000. This seems to undermine your expression of concern about the need for trained researchers. What's your comment?

Answer: An adequate cadre of investigators trained in the field of aging is essential for the continued development of aging research. At the same time, it is important to provide a sufficient amount of competing research project grant money to assure that these newly trained researchers, as well as more experienced ones, will have incentive to remain in aging research. The National Institute on Aging has tried to balance the need for additional researchers against the need to provide the highest level of funding possible for research itself. The cut of $55,000 in the revised budget represents the effect of eliminating a proposed across-the-board 5% stipend increase for NRSA supported trainees.

Question: We continue to be concerned that there are too few doctors involved in geriatric health care. What are you doing to increase their numbers?

Answer: Since it's inception the Institute has stressed the need to develop the field of geriatrics and gerontology, and has responded to these needs by supporting several special award mechanisms. These include the Geriatric Medicine and Dentistry Awards, the Academic Award, the Clinical Investigator Award, and the

Teaching Nursing Home Award, as well as National Research Service Awards (NSRAs).

The Geriatric Medicine and Dentistry Awards are designed to stimulate faculty and curriculum development in geriatric medicine, dentistry, and research; the purpose of the Academic Award is recruitment of future academic investigators for careers in research and teaching with special emphasis on geriatric medicine and related clinical disciplines. The Clinical Investigator Award provides support to promising clinically trained individuals with the goal of fostering growth of independent biomedical investigators in clinical areas relevant to aging. The recently initiated Teaching Nursing Home Award supports research on geriatric health problems in nursing homes and other clinical settings. It seeks to encourage research on health problems particularly prominent in nursing homes and among geriatric outpatients and provides an environment for the training of both research and health care professionals in areas related to aging. The NSRAs support both postdoctural and predoctoral students interested in entering the field of aging research.

The need for more training in geriatrics is not restricted to the medical sciences. The NIA is developing a new Special Emphasis Research Career Award in behavioral geriatrics to encourage the training of social and behavioral scientists to work within the emerging subfield of behavioral medicine. Behavioral medicine seeks to specify how particular health-related behaviors and attitudes promote or impede health maintenance in the middle and later years, how they interact with biological aging processes, and how they influence the effectiveness of health care.

PROTECTING THE INVESTMENT

Question: At a time when many budgets are going down, Congress has been increasing funding of the National Institutes of Health, including your Institute. We are concerned that these scarce resources be carefully and effectively used and that there be no basis for criticism of your management of this money. What assurances can you give us that your Institute is making careful and effective use of the appropriations we provide you?

Answer: The National Institute on Aging seeks to maximize the potential of research accomplished through its various programs in a variety of ways. Overall quality of extramural grant awards is, of course, assured by the standard peer review process at NIH. When determining which avenues of research might be most appropriately emphasized in terms of potential benefits gained for the funds spent, the NIA relies not only on its own program staff, but also on such advisory groups as the National Advisory Council on Aging and its intramural counterpart, the Board of Scientific Counselors. Recently the National Institute on Aging published a document entitled Toward an Independent Old Age: A National Plan for Research in Aging. This document reports the findings and recommendations of the National Research on Aging Planning Panel, whose expertise was supplemented by that of some 240 experienced scientists serving as consultants in their individual fields of speciality. The panel reviewed past and current research on aging; assessed the current state of knowledge, including progress and accomplishments in research on aging and barriers to further progress; defined needs and promising opportunities in research on aging; and made specific recommendations

to the NIA regarding major thrusts and future directions for research on aging. It is the Institute's intent to use this document as a major guide for program development over the next several years.

Question: Aside from the peer review system, what institutional arrangements do you have that serve to deter waste, fraud or abuse in the handling of federal funds?

Answer: NIA has established formal internal policies and procedures for dealing with issues of waste, fraud or abuse in all administrative and program levels within NIA. In addition, a focal point for reporting and handling these issues has been established within the Office of the Associate Director for Planning and Extramural Affairs, NIA.

NEW BUDGET FOR FY 1984

Question: There's more to the revised NIH budget than simply the specific cuts we've just discussed. There are effects, as well, and they represent an important form of reduction. For example, the January budget first, and now the April budget, assume cuts in the average award for new and competing grants below what the full average cost should be. For new grants this appears to be a difference of some $17,800 ($142,400 for the full cost vs. $124,600 in the revised budget). How will this reduction in the average cost of grants affect your Institute -- and, most importantly, to what extent will it change the scope and quality of the projects that are reviewed by your study sections?

Answer: The reduction in average cost of our competing research project grants from projected recommended levels under the April budget is 10.1 percent for direct costs and a further reduction of 3 percent because of indirect cost reductions. This will require a careful review by our program staff to identify which grants or program areas can best withstand these cuts. Our concern is that funding not be reduced to the point where researchers cannot keep pace with relevant technological advances. However, the amount budgeted for new and competing research project grants in the April budget still includes an increase in the average cost of these awards over the 1983 average cost of about 8 percent. Even when this increase is offset by the proposed reduction in indirect costs from 1983 to 1984, the 1984 average cost increases by about 5 percent over the 1983 average cost.

The reduction in the average size of competing grants should not affect the quality of the projects that are reviewed by our study sections since the grants are reviewed before any proposed reductions are imposed. After review of the projects by the study sections and funding by NIA, needless to say, a decrease in the size of the grant means that the investigator must make very hard choices about following new leads and opportunities.

Question: We understand the noncompeting continuation grants will get similar treatment, with the average grant award projected to decrease by about $12,400 below the full average cost ($143,100 full cost vs. $130,700 in the budget revision). Once again, what's the effect on your Institute -- and what will this do to the <u>scope</u> and <u>quality</u> of the projects that are reviewed by your study sections?

Answer: The effects of reducing average size of noncompeting awards are essentially the same as for competing awards. Even with this reduction the 1984 budget still includes an increase in the average cost of non-competing awards of about 6%, offset by the 3% indirect cost reduction. Continuing reductions in grant cost could effect the progress of research, and lends an atmosphere of uncertainty for investigators.

Projects in the noncompeting category are not reviewed by study sections until the end of their 3 to 5 year funding period, but any obvious changes in scope or quality in these grants would, of course, be noted and assessed by Institute staff on an ongoing basis. At the moment, there is no way to predict the effects, if any, of the proposed reductions with any certainity.

ALZHEIMER'S DISEASE

Question: We have read through your February report to the Committee on Senile Dementia of the Alzheimer's type. You indicate a number of interesting leads, including a marked loss of nerve cells in the base of the brain, high concentrations of aluminum in affected brain cells, the possible role of slow-acting, transmissable viruses, and impaired sleep in the early stages of the disease. Which of these leads is currently thought to be more important -- or are they all of equal weight?

Answer: There is considerable evidence that some of the most important current leads include defects in the synthesis and release of chemicals in the brain which enable cells to communicate with one another; defects in the brain's ability to utilize glucose; defects in certain brain enzymes; formation of abnormal proteins inside brain cells; and the accumulation of aluminum. Cell loss and the role of slow-virus might also be linked to a common cellular physiological defect. Present thinking is that these changes are interrelated and it would be difficult to predict where the major breakthrough will come from.

Our ability to achieve positive results in the study of SDAT has been enhanced by recent improvements in diagnostic instrumentation--better imaging techniques for CT scanning and the development of positron emission tomography (PET) and nuclear magnetic resonance (NMR) as tools for examining local brain metabolism--which provide promise for early diagnosis and detection of senile dementia. The recent discovery of a primate model for memory deficity similar to that of senile dementia provides an essential new tool for testing neurochemical hypotheses and various treatment regimens. Of particular interest are studies on human subjects using new techniques such as PET to examine local brain metabolism, as well as to evaluate the effects of specific pharmacotherapeutic regimens.

Question: According to your report, researchers at Albert Einstein College of Medicine seem to have made some headway with a drug called Physostigmine, which seemed to improve memory temporarily. How promising is this drug?

Answer: In and of itself, this drug may not prove to be of practical use in treating Alzheimer's patients because it is effective for only a short time; it works only in some patients and

not others; and it has some undesirable side effects. The importance of the research with this drug lies in the fact that some proportion of Alzheimer's patients show temporary improvement in memory or cognitive functioning. This result indicates that the disease lends itself to pharmacological treatment. At present, work is underway to discover other more effective and longer lasting pharmacological agents.

Question: We read in the newspaper that the drug naloxone may be better and safer than physostigmine. What can you tell us about this drug?

Answer: The newspaper accounts concerning naloxone were based on a letter submitted to a medical journal reporting the results of preliminary results based on a very limited number of subjects. In our judgment it is premature to make any statements concerning the effectiveness of this drug in treating Alzheimer's patients. We need to wait until more formal and better controlled studies report their results. Such work is presently underway in several laboratories supported by NIA.

Question: One solid conclusion of the report is that there is "A serious need for further research on the experiences and needs of families" of Alzheimer's patients. What will be your response to this statement in the report?

Answer: The NIA's Behavioral Sciences Research Program has a major emphasis on biosocial aging and health, with several ongoing grants focusing on coping with illness of various kinds. What is learned about the burdens on caretakers and about coping strategies in general can be applied to specific difficulties of Alzheimer's patients. The Teaching Nursing Home Program also provides an arena for developing related projects in this area.

Question: We note from your report you may spend about $22 million on Alzheimer's Research in fiscal 1983. How much do you plan to spend in fiscal 1984 -- and in your professional judgement is that enough?

Answer: At present the NIA's total extramural and intramural commitment to Alzheimer's disease is $9.2 million, representing a major portion of the $22 million estimated for expenditure in FY 1983 by the Public Health Service. In 1984 we anticipate the NIA will spend approximately $11.2 million. Because of recent advances there is increased interest in conducting research on Alzheimer's disease. This interest is reflected by the fact that a growing number of research proposals are approved because of their excellent scientific merit but cannot be funded within the proposed budget.

TEACHING NURSING HOMES

Question: One of your new initiatives is the so-called Teaching Nursing Home grant for research on geriatric problems in a nursing home setting. You indicate that you have awarded the first two grants under this program. To whom have they gone, what research area will be covered, and how many more grants will you award?

Answer: One Teaching Nursing Home award is to the Albert Einstein College of Medicine of Yeshiva University in New York City.

The chronic care facilities involved are Beth Abraham Hospital, Morningside House Nursing Home, and Hebrew Home for the Aged. The principal investigator, Dr. Robert Katzman, is Professor and Chairman of Neurology at the Albert Einstein College of Medicine. One component of the project will evaluate the effectiveness of physostigmine, a drug which may improve memory in patients with senile dementia. Another research project will examine correlations between cognitive changes in Alzheimer's disease and genetic factors. This study has implications for identifying the causes of Alzheimer's disease. Other projects will focus on the causes of osteoarthritis in the elderly and on how problems of balance and gait relate to falls in the elderly.

The other Teaching Nursing Home award is to the Philadelphia Geriatric Center. The consortium of institutions involved in this project includes the Medical College of Pennsylvania and the University of Pennsylvania. The principal investigator, Dr. Donald Kaye, is Professor and Chairman of the Department of Medicine at the Medical College of Pennsylvania. The research program includes a study to determine factors which affect an older person's risk of acquiring a urinary tract infection, a study on the benefits of exercise for nursing home residents, testing of an intensive cognitive therapy for stroke rehabilitation; application of the PET (positron emission tomography) scan in the study of dementias; and investigations on the prevalence and causes of sleep apnea (frequent interruptions of breathing during sleep that occur among many elderly and which, in some cases, can be life-threatening).

The medical research community's interest in the Teaching Nursing Home Program has remained strong, and the NIA plans to make up to three additional Teaching Nursing Home Awards in FY 1983. The number of additional awards in future fiscal years will depend on both the availability of funds and the quality of applications reviewed.

Question: To what extent may we dare to hope that this program will contribute to containment of the mounting costs of nursing home care?

Answer: Advances in clinical management and possible prevention of the chronic diseases of aging should result in diminished nursing home costs. For example, senile dementia (which is the focus of three TNH research subprojects) may account for as much as 50 per cent of nursing home admissions. Even marginal improvements in treatment or management of dementia could result in significant savings in the $25 billion currently spent annually for nursing home costs. Similiar savings could be expected from advances in prevention or treatment of osteoarthritis, injuries associated with falls (such as hip fracture), and urinary tract infections in nursing homes, each of which is the subject of current Teaching Nursing Home research. However, the magnitude of these savings, and the speed with which they occur, will remain uncertain until these research advances have occurred and are applied in practice.

BALTIMORE STUDY/BIOFEEDBACK

Question: The Baltimore Longitudinal Study of Aging has shown that some elevatfon of blood sugar levels seems to be a normal part of the aging process and, you say, does not represent a disease

state. If that's the case, to what extent have you gotten this information into the hands of practicing physicians so they can use it in diagnosing conditions of the elderly?

Answer: Age associated increases in fasting blood sugar levels, as well as age-related decrements in oral glucose tolerance, both in the absence of clinically detectable disease (diabetes mellitus), were first reported in the scientific literature by Gerontology Research Center investigators in 1965. These studies, based on observations made on healthy volunteer subjects of the Baltimore Longitudinal Study of Aging, have subsequently been confirmed and expanded. In 1979, a Diabetes Data Group, organized and coordinated by NIH, reviewed and reaffirmed the validity of these findings, and recommended the adoption of new standards, including age adjustment, for assessing normality of performance with respect to blood sugar. These new standards have since been accepted by the American Diabetes Association and have been widely promulgated and routinely applied in the community of general medical practice.

Question: You state that relaxation training and biofeedback can "significantly" lower the blood pressure of hypertensives. Has this information been passed on to practicing physicians?

Answer: The application of behavioral interventions, including relaxation and biofeedback, to the amelioration of hypertension is an area of active research at the Gerontology Research Center, but is not yet sufficiently tested or validated for immediate application to general medical practice. In the course of the next few years, however, a sufficient body of research and demonstration data should be in place to permit both identification of those classes of hypertensives who will derive greatest benefit from behavioral treatments, as well as the design of treatment regimens most compatible with the realities of general medical practice. In the latter case, it should be noted that behavioral treatment modalities are at present not commonly utilized in general medicine. Accordingly, should further research reveal that treatment of hypertension by behavioral interventions is as effective as present data suggest, considerable efforts will be required to educate the practicing physician in this new approach to therapy.

Questions Submitted by Senator William Proxmire

NONCOMPETING VS. NEW PROJECTS

Question: Dr. Ringler, I'm somewhat disturbed by a shift in the balance between noncompeting research grants and new competing projects at the Institute on Aging between 1982 and 1984. Under your current budget plan, during that span of time noncompeting grants will increase by 45.6 percent while new competing research will decline by 17.8 percent. Why have you followed this course?

Answer: This is not a deliberate policy, but rather a function of the fact that grants are generally awarded for three years. In FY 1982 and FY 1983 combined, we expect to fund a total of 332 competing research projects. By FY 1984, only 14 of these projects will have dropped out. In a fiscally constrained environment, the large number of noncompeting awards has an adverse

impact on the number of competing awards which can be made. The proposed reductions in average cost are an effort to reduce this impact as much as possible while still maintaining the quality and integrity of our research.

ALZHEIMER'S DISEASE

Question: Dr. Ringler, on page 3 of your prepared testimony you describe some of the work that has been done on senile dementia of the Alzheimer's type. Yesterday the Director of the National Institute of Neurological and Communicative Disorders and Stroke made it clear in his testimony that his Institute is charged with research for the diseases that usually strike the elderly and specifically mentioned Alzheimer's disease. Could you differentiate the work of your two Institutes in this area?

Answer: The legislative mandate of the National Institute on Aging (NIA) directs the Institute to foster scientific research programs that deal with not only the normal aging process but with the diseases of the aged and conditions which impact on the quality of life.

The NINCDS has responsibility for many neurological disorders which may effect all age groups. However, the legislative mission of NIA specifically directs the Institute to focus on the problems of the aged by supporting research as well as coordinating all age-related research activities throughout the DHHS.

Among the many age-related disabilities that require long-term care, those related to the dementias have the most signigicant implications for public policy relating to priorities for biomedical research and health care services. It is generally accepted that there are age-related changes in brain functioning, just as there is some loss in physical ability. Failure in central nervous system (CNS) functioning (e.g., decrements in hearing, vision, taste, motor skills, and cognitive functioning) profoundly affect the quality of life for the aged. Such changes often influence the attitudes of others toward the aged, affect the individual's self-image, and often determine the nature and quality of health care services. Failure in cognitive functioning is one of the principal indications for institutionalization of the elderly.. Such care is extremely expensive, impersonal and custodial and often leads to further deterioration of health and, ultimately, to death.

The issue of whether brain changes in Alzheimer's disease and dementing disorders represent an accelerated form of normal aging has not been resolved, but evidence suggests that in most cases the morphological changes in old age differ quantitatively, not qualitatively, from those in senile dementia of the Alzheimer's type. Therefore, clinical distinction between normal and pathological brain aging may be difficult because of the many common features in the structural and biochemical changes. Of the many brain impairments in the aged, decreased cognitive functioning is generally accepted to be the most consistent and serious problem. In its most severe form cognitive impairment is the hallmark of senile dementia. Therefore, brain phenomena related to cognitive impairment or brain changes related to memory decline has been the principal focus of NIA's extramural Neuroscience Program since 1977.

During the period since 1977 the Institute has developed a comprehensive research program related to Alzheimer's disease. Other agencies within the DHHS such as NINCDS, NIMH, and NIAID share an interest in Alzheimer's disease with NIA. In 1979 the NIA was designated the lead agency by the Secretary of DHHS to coordinate a Department-wide initiative on this disease. In that period the Institute has devoted a larger proportion of its extramural funds to this disease than to any other single disease. In FY 1982 nearly 10% of the total NIA budget supported research on Alzheimer's disease and other dementias of aging. In FY 1984, this figure is expected to increase to slightly over 11%.

TRAVEL

Question: Why is it necessary for you to increase your travel budget by 18.5 percent in fiscal year 1984?

Answer: The primary reason for the increased travel is a substantial increase in the number of grant applications which must receive site visits. The Institute has recently experienced an upsurge in the number of program project (P01) applications it is receiving, all of which must receive site visits before they can be considered for funding. Similarly, the new Teaching Nursing Home (TNH) program has been highly successful in generating applications. These also must be reviewed and inspected on-site. While site visits are expensive generally, those for TNHs are especially so. They require large teams of site visitors with diverse specialities in order to assure adequate review of the complex, multi-faceted TNH applications.

CONSUMER INFORMATION CENTER

Question: You plan to more than double your contributions to the Consumer Information Center next year. Why are you proposing such a sharp increase and how will the $80,000 you are requesting be used?

Answer: This expense is a GSA tap which helps support distribution of consumer information literature developed by the various agencies of the Federal government. It is my understanding that GSA taps all Federal agencies on a pro-rated basis. The increased support proposed in the NIA FY 1984 budget for the Consumer Information Center represents a shared mandatory increase which was added to the NIH budget.

EXTRAMURAL FUNDING

Question: Provide for the record a breakdown of extramural funding for research in your biomedical and clinical, behavioral sciences, and epidemiology, demography and biometry research programs for the five fiscal years through 1984. We'd also like the same information for your training activity.

Answer: A table containing the requested material is provided below.

	Obligations in Thousands Fiscal Year				
	1980	1981	1982	1983 Est.	1984 Est.
Biomedical & Clinical					
Research	$36,504	$40,465	$45,694	$53,158	$55,746
Training	1,650	1,583	1,268	1,341	1,202
Total	38,154	42,048	46,962	54,499	56,948
Behavioral Sciences					
Research	9,665	9,471	9,926	10,422	10,943
Training	1,126	1,015	1,018	1,077	966
Total	10,791	10,486	10,944	11,499	11,909
Epidemiology, Demography & Biometry					
Research	3,353	3,422	3,248	3,410	3,589
Training	--	--	--	--	--
Total	3,353	3,422	3,248	3,410	3,589

DIVISION OF RESEARCH RESOURCES

STATEMENT OF DR. BETTY H. PICKETT, DIRECTOR

ACCOMPANIED BY:

DR. JAMES B. WYNGAARDEN, DIRECTOR, NIH
DR. JAMES F. O'DONNELL, DEPUTY DIRECTOR, DRR
H. RICHARD MILLER, ASSISTANT DIRECTOR, DIVISION OF FINANCIAL MANAGEMENT, DFM
ANTHONY ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET, DHHS

BUDGET REQUEST

Senator WEICKER. The next witness will be from the Division of Research Resources.

The committee will stand in recess for 5 minutes.

[A brief recess was taken.]

Next, we will hear from the Division of Research Resources which deals with enriching the quality of the research environment.

The revised budget request for research resources is $26.7 million below the January budget and also is about $12 million below even the fiscal year 1983 appropriation. The revised budget includes some stiff cuts for this agency.

And here to testify in support of the administration's request is Dr. Betty Pickett, the Director.

We welcome you before the committee.

Please proceed with your statement, and we will proceed to questions.

Dr. PICKETT. Let me start by introducing Dr. James O'Donnell who is the Deputy Director of the Division of Research Resources.

It is a pleasure to appear before this subcommittee for the first time as Director of the Division of Research Resources to present the President's request for the fiscal year 1984 appropriation for this entity.

The Division, now over 20 years old, provides, as you said, for the development and enhancement of research resources which contribute importantly to the environment in which modern biomedical research is performed.

The DRR serves all of the institutes of NIH and consequently, to some extent, all of the areas of research that NIH supports.

Within its five activities, the Division supports: Clinical research centers where new knowledge from the laboratory can be applied to the human health care; centers providing sophisticated instrumentation, using advanced technology, such as new computer methods, new tools for advanced analysis of biological materials; it provides support for centers for the development, study, and breeding of the animal models so critically needed for an understanding of human diseases; provides

flexible noncategorical support for many of the institutions supported by PHS research grants; supports the upgrading and replacement of key instrumentation in our country's biomedical research laboratories; and finally provides research support for over 600 faculty and more than 1,200 students at academic institutions which heavily serve U.S. minority populations.

These diverse, but inter-related research resources facilitate the conduct of more than 15,000 research and research training projects and subprojects supported by the NIH research institutes and other PHS agencies.

In 1982, over 5,500 PHS research grants supported at a cost of over $659 million were awarded to institutions for researchers who used these resources. Approximately 30 percent of all NIH research grants were for the work of researchers who used DRR resources.

Finally, research investigations related to approximately 26 percent of the dollars expended for NIH research grants were facilitated by these resources in fiscal year 1982.

1984 BUDGET REDUCTIONS

I would like now, in the interest of time, to turn to the questions that you enumerated at the outset of this hearing. I would like first to address the impact of the change needed to provide the 5,000 research grants on DRR.

The biomedical research support grant was the most sharply impacted by the internal change in the administration's budget for NIH for 1984. As you noted earlier, it was cut by some $24.7 million. Smaller cuts were taken in two other programs.

In the centers programs, we have 161 centers. An approximate 1½-percent cut was taken in the overall dollar total for centers. A reduction of 2½ percent was specifically directed at the largest component, the clinical research centers.

A very small cut was taken in our training programs to reflect the maintenance of the stipend level of the preceding year.

With respect to clinical trials, none are supported by DRR, so there will be no impact.

Concerning the roller-coaster effect, my answer to that would have to be similar to those who preceded me. The investigators who use the DRR resources are, of course, part of the pool of those conducting investigator-initiated research. So the roller-coaster effect would impact the population served.

The reduction in average costs of grants, competing and noncompeting, I believe would affect the pool which supplies the biomedical research support grant since the size of the biomedical research support grant is computed on the basis of an institution's research grant base of allowable PHS grants.

Senator WEICKER. Well, that's quite a cut, isn't it, as far as your Division is concerned.

Dr. PICKETT. It is a large cut, yes.

Senator WEICKER. What do you think?

Dr. PICKETT. I think it is a large cut.

But I believe that it fits in with the administration's priorities of supporting the individual investigator-initiated efforts.

The BRS grants support some of those same investigators, perhaps at different phases in their investigative career. Despite the cut in the BRS grant we still will have a BRS formula grant, and some flexible, noncategorical funds will be available, in spite of the cut, to the investigators who need them.

The portion of the BRS activity that is related to instrumentation, I should hasten to assure you, will not be cut in this effort. That was part of the administration's policy guidelines at the time the revision in the budget was made.

BRSG ELIGIBILITY THRESHOLD

Senator WEICKER. In our fiscal 1983 committee report, we directed that you not raise the research base threshold for institutions wishing to receive the assistance under the biomedical research support grants. Your proposal would have increased the base from $200,000 to $500,000, knocking out schools and other research facilities that did not meet the $500,000 standard.

We now find out you propose raising the threshold to $350,000 in fiscal 1983 and plan to raise it to $600,000 in fiscal 1984. What are your reasons for making this recommendation? And we assume your plans for fiscal year 1983 are still in the recommendation stage and are not an accomplished fact.

Dr. PICKETT. You are correct, Senator, that those plans are still in the recommendation stage.

I would like to take a minute to clarify what the situation is in terms of the 1983 awards because I believe, justifiably, there is some confusion about exactly what we are doing.

We have for the time being, and awaiting this hearing and the recommendations of this committee, held the threshold at $200,000 so that all institutions who have an eligibility at $200,000 either have already been awarded a portion of the fiscal 1983 award or are in the process of receiving it.

In 1983, we have not, so far, raised the threshold. Our proposal to move the threshold down from $500,000 to $350,000 in 1983 was really in response to the concerns expressed by some of the smaller institutions. And as you know, we have prepared a report to this committee which describes the impact of the proposed shift on those smaller institutions.

The rise to $600,000 proposed in 1984 is based simply on the application of the indexing proposed in the plan, which would relate the payment basis to the NIH 1983 budget which we received in the continuing resolution.

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The originally proposed $500,000 threshold was predicated on the President's budget for 1983. As you know, the ultimate budget for 1983 was somewhat higher than the President's budget and, therefore, when the indexing is applied and the calculation is made, the proposed threshold for 1984 comes out to be somewhat higher than we had originally anticipated.

And I believe all of the plans and calculations that were made in the preceding year underlying this proposed change were based on the President's submission for 1983.

IMPACT OF CHANGING THE ELIGIBILITY THRESHOLD

Senator WEICKER. Your report says nothing about the impact of your cutoff on the nursing, dental, and pharmacy schools, as well as others, that would be dropped from the program. What sorts of research which might prove promising are no longer to be supported?

I understand that 40 schools would lose eligibility under the new $350,000 standard.

Dr. PICKETT. I can't give a detailed accounting of the kinds of research that would be done in those schools. I would be glad to give it for the record, sir.

[The information follows:]

IMPACT OF CHANGING THE ELIGIBILITY THRESHOLD

Institutions use biomedical research support grant (BRSG) funds for a variety of self-determined purposes, therefore, it is difficult to project, before the fact, the impact on specific research activities conducted in the institutions that could be affected by a change in the eligibility threshold to $350,000. However, examination of the latest available BRSG annual progress reports from 1981 indicates that BRSG funds have been used for the following kinds of research at nursing, dental, and pharmacy schools.

Dental schools.—Mechanical properties of tooth replacement materials; the formation and control of dental plaque; and bone and tooth mineralization.

Pharmacy schools.—Stereoselectivity of drugs; neuropharmacological and behavioral study of phenylcyclidine, a street drug commonly known as angel dust; and tissue distribution of DES.

Nursing schools.—Sociology of self-care agencies for adolescents; patient sensations related to tracheotomy; and anxiety studies of birthing environments.

SHIFTING RESEARCH ACTIVITY

Senator WEICKER. It seems to me that the emphasis, just by virtue of the figures, has to shift, however, to large schools with a big research base.

Dr. PICKETT. The purpose behind the shift, and the study underlying the shift has been going on since, I believe, 1979. The purpose was to meet the intent of both Houses of Congress, that those institutions engaged most intensively in research activity, or most heavily engaged in research, be provided this flexible, noncategorical source of funding to meet the needs of the institutions conducting PHS-funded research.

The rise in average cost of the research grant over the years has impacted the calculation very severely. The average cost of the research grant has gone up from something like $58,000 in 1976 to about

$100,000 today. So a $200,000 threshold today could represent a much smaller research program than in the years when the average grant was much smaller.

Senator WEICKER. Well, let me cross-pollinate my other disciplines here in the U.S. Senate with the problem that we are discussing. I have the Senate Small Business Committee, and I don't know if this comes as a surprise to you or not, but 85 percent of all innovation in the United States comes out of small business compared to big business. Ninety percent of the new employment comes out of small business rather than big business.

What I am saying is that I think it is terribly important that the smaller endeavors be the ones that are not cut, but get the help that they need.

I think those principles would apply in the scientific area as well as the business area. And certainly, there is a certain restlessness, a certain hunger, on the part of the small that drives them far more than those that are fat and happy and satisfied.

So I would hope that we don't lose sight of these types of institutions.

Ms. Ingram told me, for example, she was talking to the dean of the pharmacy school at the University of Connecticut. And that is a very small school. It satisfies the criteria, but the fact is, I gather, there are only 28 of its kind throughout the country?

Ms. INGRAM. Something like that.

Senator WEICKER. So I worry about these types of institutions, even those within the larger institutions.

Well, I want to take a careful look at this situation as it relates to your division. It is clear that a good chunk of the dough to finance the 5,000 grants came out of this Division.

PREPARED STATEMENT AND SUBMITTED QUESTIONS

I have further questions for response to the record.

Dr. PICKETT. Thank you.

[The information follows:]

Statement of Dr. Betty H. Pickett

It is a pleasure to appear before you for the first time as Director of the Division of Research Resources to present the President's request for the FY 1984 appropriation for Research Resources.

The Division was established 20 years ago to provide for the development, support, and administration of research resource programs. Research resources maintain the quality of the environment in which modern biomedical research is performed. The excellence of science today depends on essential, costly resources, such as sophisticated instrumentation, that utilize new technologies, clinical research centers for the application of laboratory advances to human health care, large-capacity computers for the analysis of data, and centers for the development and breeding of colonies of unique animal models critically needed for the study of human disease.

Five Division programs enhance and strengthen the research environments of institutions engaged in health-related research, and facilitate the conduct of more than 15,000 research and research training projects and subprojects supported by the NIH research Institutes and other PHS agencies. The five programs are the General Clinical Research Centers Program, Biotechnology Resources Program, Animal Resources Program, Biomedical Research Support Program, and the Minority Biomedical Research Support Program.

The 74 General Clinical Research Centers provide the clinical settings for investigators conducting research supported by project grants from the categorical Institutes. In 1982, nearly 4,000 investigators carried out 3,114 research projects in the Centers, supported by approximately $400 million of NIH and other PHS grants. The research conducted within the Centers contributes very importantly to the major initiatives including nutrition, diabetes, digestive diseases, prevention, and population research which cut across the boundaries of the separate research Institutes.

Noteworthy research achievements continue to take place within the Centers. Recent important advances in the understanding of Reye's syndrome have resulted from studies of children who are unable to oxidize fatty acids because of a defect in carnitine metabolism. In one patient, a low-fat diet, coupled with carnitine therapy, has led to substantial improvement. Bone marrow transplants, now used in the treatment of leukemia and aplastic anemia, have been employed in GCRCs to correct congenital immunodeficiencies. In treatment of diabetes, the programmable pumps developed at GCRCs allow automatic injections of insulin.

The Centers also provide an ideal setting for attracting, training, and retaining research-oriented clinical manpower. For some years, the DRR has supported an important activity called the Clinical Associate Physician Program, which has fostered careers in clinical research for young physicians within the GCRCs. The Centers provide medical students and residents opportunity for observing and participating in clinical investigations in an optimal research environment. Within the Centers, the DRR has supported the development of a minicomputer system called CLINFO, which facilitates clinical research by providing investigators an easy-to-use data analysis system.

Over the years, a key element in maintenance of appropriate environments for biomedical research has been the flexible, noncategorical funding provided by the Biomedical Research Support Grant (BRSG). The amount of these funds is linked to the overall PHS

funding at the institution. The BRSG enables institutions to respond quickly to critical research needs. The most popular uses of these funds have been for central facility improvement or renovation, for purchase of medium- or low-priced equipment, support for pilot projects, and for temporary phase-in or phase-out support for projects in an interim status.

The Shared Instrument Grant Program (SIG), begun in 1982, is an offshoot of the Biomedical Research Support Grant. SIG is an attempt to respond to institutions' problems of research equipment obsolescence and shortage. In 1982 $3.7 million provided 23 grants for shared instruments. In 1983 the Congress provided an additional $10 million for shared instrumentation awards. $9 million will be provided under SIG; $1 million has been set aside to provide for the special equipment needs of the institutions supported under the Minority Biomedical Research Support Grant Program.

Through the regional Primate Research Centers, DRR provides still other opportunities for the advancement of biomedical research. The seven Centers, each affiliated with a host academic institution, provide core operational support for an array of research projects funded largely by categorical NIH Institutes, foundations, and other federal agencies. Research is conducted in areas such as reproductive biology, infectious diseases, behavioral sciences, neurosciences, toxicology, and nutritional and metabolic diseases. More than 500 affiliated, collaborative, and visiting scientists supported by research project grants use the resources of the Centers. Biological specimens are provided for scientists on a regional and national basis, and domestic breeding of certain species is conducted by all seven of the Centers. Each of the Centers has its own research foci, but key problems turn out to be of shared interest. The identification in some of the Centers of naturally occurring models of human diseases such as cystic fibrosis, leprosy, and urological disorders holds great promise for advances in human health. Collaboration among the centers on at least two of these models will, we predict, yield results of high significance. Specifically, a recently discovered case in the sooty mangabey of lepromatous leprosy, similar to Hansen's disease in the human, will likely lead to the most useful animal model for this disease yet to be discovered. A very recent development, the spontaneous occurrence at two Primate Research Centers of a disease in rhesus monkeys which appears similar in some ways to the human disease called Acquired Immunodeficiency Syndrome (AIDS), is now under study by Center scientists.

Through animal diagnostic laboratories funded by the Division, scientists are developing knowledge which will assure improved health programs for laboratory animals. Naturally occurring diseases are investigated to find their causes and methods of control, treatment, and prevention. Other projects establish and improve unique colonies of animals essential for research on problems of human health. Institutional animal resource improvement projects help institutions upgrade their animal facilities and develop centralized programs of animal care in support of their biomedical research programs. A major objective is to enable institutions to comply with the Animal Welfare Act and DHHS policies on the humane care and treatment of animals.

The Biotechnology Resources Program (BRP) enriches biomedical research by developing and providing sophisticated instruments and technologies, accessible to scientists on both national and regional bases. The Biotechnology Program includes support for development in computer and information technology, biomedical engineering, and

sophisticated systems for analyses of biomolecular and cellular structure and function. Important advances in so-called knowledge engineering and artificial intelligence which bring together bodies of knowledge in clinical or biological research have produced a series of "expert systems" which can aid in decision making in research and treatment. In the clinical area, computer programs can now provide systems for "guidance" and "advice" to physicians which assist them in the diagnosis of a series of medical problems in, for example, internal medicine, infectious diseases, and rheumatology.

The BRP supports a national computer network which develops and provides access to shared tools for biomedical research information management and analyses and for scientific communication and collaboration. This network supports the research of over 800 biomedical scientists at more than 40 institutions throughout the United States. Further, the Biotechnology Resources Program has supported the development of other computer systems which enable determination of molecular structure from various chemical-physical measurements. Still another computer-based system enables the clinical investigator to manipulate 3-D images from CAT scanners. In the biomedical area, new microcomputer-based devices are being developed which may assist in the rehabilitation of cerebral-palsied patients or those paralyzed by spinal-cord injury.

Powerful new tools such as million-volt electron microscopes, nuclear magnetic resonance systems, and new types of x-ray resources called synchrotron radiation sources have been developed to expand scientists' capacity to analyze complex biological materials. For example, phosphorous NMR is being used to investigate the metabolic state of human kidneys prior to transplantation. Mass spectrometry is being used to study the structure of an antigen to leprosy bacillus. Knowing that structure, scientists have been able to develop specific tests for leprosy in humans. These tests are now used for early diagnosis in the United States, Thailand, and India.

The Minority Biomedical Research Support Program is somewhat different in emphasis from the other DRR activities in that it provides a significant opportunity for developing a previously untapped research manpower pool--faculty and students at predominantly ethnic minority institutions. The Program provides a range of opportunities: for faculty to initiate research; for undergraduates to participate in faculty research projects; and for upgrading research laboratories in MBRS institutions. Currently about 610 faculty members, 904 undergraduates, and 328 graduate students are participating. We now see some encouraging signs that the investment in this program is beginning to yield returns: faculty and students from MBRS-supported institutions are making more presentations at scientific meetings; about 40 percent of current MBRS graduates choose to go on to graduate school; about 40 percent choose medical or dental school; most of the rest accept jobs related to health. The first example of "reseeding" the Program occurred this year with the appearance of an MBRS-produced Ph.D. as the Director of an MBRS program at a small southern university. Some MBRS-supported investigations have received national attention. For example, studies characterizing irreversibly sickled cells will help in the search for a cure for sickle cell anemia; new anti-hypertensive drugs with fewer side effects have been developed from work conducted by one of the program's earliest Ph.D. graduates.

Mr. Chairman, our request for the Division of Research Resources for FY 1984 is $201,837,000. I would be pleased to answer your questions.

Biography of Dr. Betty H. Pickett

Name: Betty Horenstein Pickett, Ph.D.

Date and Place of Birth: February 15, 1926
Providence, Rhode Island

Marital Status: Married to James McPherson Pickett, 1952

Education:

1945 - A.B. (Psychology) Magna cum laude, with High Honors in Psychology, Brown University

1947 - Sc.M. (Psychology), Brown University

1949 - Ph.D. (Psychology), Brown University (Thesis: Performance of Conditioned Responses as a Function of Strength of Hunger Drive)

Positions Held:

October 1982 - Present	Director, Division of Research Resources
July 1982 - September 1982	Deputy Director, National Institute of Child Health and Human Development
July 1981 - July 1982	Acting Director, National Institute of Child Health and Human Development
July 1979 - July 1981	Deputy Director, National Institute of Child Health and Human Development
January 1979 July 1979	Deputy Director-Designate, National Institute of Child Health and Human Development
June 1977 - January 1979	Associate Director for Extramural and Collaborative Research Program, National Institute on Aging
March 1977 - June 1977	Associate Director for Extramural and Collaborative Research Program (Designate), National Institute on Aging
July 1975 - March 1977	Acting Director, Division of Extramural Research Programs, National Institute of Mental Health
September 1974 - July 1975	Director, Division of Special Mental Health Programs, National Institute of Mental Health
February 1968 - September 1974	Deputy Director, Division of Extramural Research Programs, National Institute of Mental Health
July 1966 - February 1968	Chief, Cognition and Learning Section, Behavioral Sciences Research Branch, Division of Extramural Research Programs, National Institute of Mental Health

August 1963 - July 1966	Executive Secretary, Research Career Program, Institute of Mental Health
August 1962 - August 1963	Research Consultant to Mental Health Unit, Region #1, Public Health Service, Department of Health, Education, and Welfare
March 1961 - August 1962	On leave and resident in Stockholm, Sweden (during husband's year of study at Royal Institute of Technology)
December 1959 - March 1961	Executive Secretary, Experimental Psychology Study Section, Division of Research Grants, National Institutes of Health
March 1958 - December 1959	Executive Secretary, Behavioral Sciences Study Section, Division of Research Grants, National Institutes of Health
March 1953 - March 1958	Professional Associate, Psychological Sciences, Bio-Sciences Information Exchange, Smithsonian Institution, Washington, D.C.
February 1952 - June 1952	Lecturer in Psychology, University of Connecticut, Department of Psychology
September 1951 - December 1951	Assistant Professor, University of Nebraska, Department of Psychology
September 1949 - June 1951	Assistant Professor, University of Minnesota, Duluth Branch, Department of Psychology

Membership on Task Forces, Committees:

EEO Counselor, NIMH, 1970-1972

Civil Service Commission Board of Examiners, Health Scientist Administrator Panel, 1970-1976; 1981

Special Assistant to the Director, National Institute of Mental Health, for Women's Action Program, June 1971-1972 (Purpose: To establish the NIMH Women's Council)

National Institute of Mental Health Research Task Force, May 1972 - November 1974, Co-chairperson Psychology Study Group

Grants Associate Board, Division of Research Grants, National Institutes of Health, 1973-1974; 1978-1980

Director's Research Advisory Group, National Institute of Mental Health, September 1974 - April 1977

Interagency Committee for the Implementation of the Research on Aging Act of 1974, Research and Planning Subcommittee, October 1974 - May 1974

Task Force to Study the Research Program of Saint Elizabeth's Hospital, July 1974 - December 1975 (Task Force Chairperson)

National Institute of Mental Health Outside Work Activities Task Force, March 1976 - June 1976 (Task Force Chairperson)

National Institute on Alcohol Abuse and Alcoholism Task Force on Grants and Contracts to National Organization, June 1976 - December 1976

National Institutes of Health Extramural Associates Program, 1978

Chairman, National Institute of Mental Health Search Committee for Chief, Laboratory of Psychology and Psychopathology, 1978

Member, National Institutes of Health, Search Committee for Associate Director for Administration, 1979

Member, National Institutes of Health, Alcohol, Drug Abuse and Mental Health Administration Interagency Committee on Health and Behavior, 1980

Member, National Cancer Institute Search Committee for Deputy Director, 1980

Member, National Institute of General Medical Sciences Search Committee for Associate Director for Program Activities, 1981

Member, National Institute of Dental Research Search Committee for Director, 1982

Societies:

American Psychological Association
Eastern Psychological Association
Psychonomic Society
Association of Women in Science
American Association for the Advancement of Science
Society for Research in Child Development
Academy of Behavioral Medicine
Sigma Delta Omicron, Graduate Women in Science

Honors:

Phi Beta Kappa, 1945
Sigma XI, 1945
University Fellowship, Brown University, 1947-48
Miss Abbott's Alumni Fellowship, Brown University, 1948-49
A.B., Brown University, Magna Cum Laude, high honors in psychology
DHEW Superior Service Award, 1972
DHEW Distinguished Service Award, 1975
FEW Award for Distinguished Service in Support of Equal Opportunities for Women, 1975
Citation from Graduate School, Brown University, for scientific and professional achievement, 1978
Harold M. Hildreth Award (for distinguished contribution to psychology in the public service, 1979, American Psychological Association)

Elected Fellow, AAAS, 1981
Recipient of SES Bonus Award for Outstanding Performance, 1981
Recipient of SES Bonus Award for Outstanding Performance, 1982

Research Interests:

Experimental Psychology
Research Administration

Publications:

Kimble, G. A., and Horenstein, Betty R. Reminiscence in motor learning as a function of length of interpolated rest. J. Exp. Psychol., 38, 239-244, 1948.

Schlosberg, H., Duncan, M. C., Daitch, and Horenstein, Betty R. Mating behavior of two live-bearing fish Xiphophorus hellerii and platypoecilus maculatus. Physiol. Zool. XXII, 148-16, 1949.

Horenstein, Betty R. Performance of conditioned responses as a function of strength of hunger drive. J. Comp. Physiol. Psychol., 44, 210-224, 1951

Pickett, J. M., and Pickett, B. H. Communication of speech sounds by a tactual vocoder. J. Speech & Hear. Res., 6, 207-222, 1963

Questions Submitted by the Subcommittee

MBRS NAME CHANGE

Question: You propose to change the name of Minority Biomedical Support Program in the bill language to "Minority Biomedical Research Support." What is the significance of adding the word "Research" to the official title--and who requested it?

Answer: In recognition of the research accomplishments which had been made by the investigators funded by the Minority Biomedical Support (MBS) Program in just ten years since its inception, and at the suggestion of the MBS Program Directors, staff of the Division of Research Resources requested the Director of the National Institutes of Health to approve a name change for the Program. On February 24, 1982, the program was officially designated the Minority Biomedical Research Support Program.

SHARED INSTRUMENTATION AT MINORITY INSTITUTIONS

Question: Our committee report suggested you set aside a portion of funds under your Shared Instrument Grant Program for institutions participating in the Minority Biomedical Research Support Program. How are you implementing this suggestion?

Answer: As a result of the committee report, a decision was made to set aside up to $1 million for an instrumentation grant program for Minority Biomedical Research Support (MBRS) grantees only. An announcement was mailed out to eligible institutions for an application receipt date of April 1, 1983. Forty applications were

received and are currently under review. A special meeting of the National Advisory Research Resources Council has been scheduled for September 12, 1983. Awards will be made prior to September 30.

AUTOMATIC DEFIBRILLATOR

Question: Your justification reports on a number of interesting accomplishments, such as development of an automatic defibrillator that can be implanted without major chest surgery, reducing the cost of the procedure and patient time spent in the hospital. How soon will this development be available for general use, and what arrangements have been made for getting the information into the hands of the practicing physician?

Answer: The automatic defibrillator is now at the stage where a manufacturer, the INTECH Company, is making a preliminary request for FDA approval. In July, INTECH will submit clinical data, with assistance from a group of physicians, and request the FDA to license the product for the treatment of patients suffering from severe recurrent ventricular tachycardia or individuals who have had ventricular fibrillation. All the clinical data are available to document its safety and effectiveness for treating these two types of arrhythmias. These individuals have not had myocardial infarction, but suffer from recurrent ventricular arrhythmia. There have been 30 publications to date for the purpose of explaining the latest developments on the automatic difibrillator to the practicing physician.

In another group of patients, those who have had myocardial infarction, further evaluation of the device will be required. Up until now, it has not been possible to identify individuals who are prone to develop ventricular fibrillation following myocardial infarction. But now it is believed possible to identify such patients at high risk of fibrillating within one year after infarction. It is critical that continued support be provided to test out the device's usefulness in this important subset of myocardial infarction patients.

SUCROSE POLYESTER

Question: You have developed a calorie-free fat substance to combat obesity. How soon will this development be available for general use, and what arrangements have been made for getting the information into the hands of the practicing physician?

Answer: Initial testing of this substance, sucrose polyester, has been carried out in humans, but further testing and evaluation is still necessary. No estimate can be obtained when the FDA will allow this substance to be marketed. FDA approval is being sought by Proctor and Gamble.

Twenty-seven publications have appeared in scientific journals on this substance, the majority of articles originating from the Adult General Clinical Research Center (GCRC) at the University of Cincinnati. A press briefing was conducted by the Division of Research Resources at the University of Cincinnati GCRC, July 1982. In addition, two articles have appeared in the Research Reporter of the Division of Research Resources.

1984 FUNDING PLANS FOR PRIMATE CENTERS

Question: Your Division funds seven Centers nationwide that provide non-human primates, such as the rhesus monkey, for use in research on human health problems. What are your plans for operating and funding the seven primate centers in fiscal 1984?

Answer: The Division of Research Resources has no plans for major changes in the operation and resource funding of the seven Primate Research Centers in FY 1984. The budget request for the Primate Research Centers in 1984 is $20,300,000.

PRIMATE SUPPLY

Question: Do we have a sufficient supply of primates for research in this country?

Answer: In most instances, yes, but a shortage of certain species and specific age ranges of primates most suitable for many biomedical research projects continues to exist.

Question: If not, what are you doing about the problem?

Answer: All of the Primate Research Centers have established domestic breeding programs for various species, with the goal of near self-sufficiency for the Program within five years. The Laboratory Animal Sciences Program supports the production of rhesus and a few cynomolgus monkeys. The supplies are meeting most of the needs for these species in the NIH extramural community. In addition, a number of other domestic primate breeding programs have been established by various agencies to meet their needs.

Question: To what extent do we import primates from abroad -- and what is the status of this supply?

Answer: Certain species, including the cynomolgus macaque (Macaca fasicularis), baboons and New World species are currently available from their countries of origin. These species are imported for use in valid biomedical research in various laboratories throughout the United States. These importations, coupled with domestic production, are generally adequate to meet most of the current biomedical research requirements.

GUIDE FOR THE CARE AND USE OF LABORATORY ANIMALS

Question: We note you are revising or updating your "Guide for the Care and Use of Laboratory Animals." Is this routine, or does it reflect pressure from animal welfare groups?

Answer: The "Guide for the Care and Use of Laboratory Animals" has been updated about every four years since it was first published in 1963. The last edition was published in 1978. Therefore, we requested the Institute of Laboratory Animal Resources (ILAR), National Academy of Sciences, to begin revision and awarded the Institute a two-year contract in 1982 for this project.

We are aware of the concerns of animal welfare groups about the care and use of experimental animals. We have also heard from numerous scientists concerned about various recommendations, as well

as omissions, in the "Guide" since its 1978 publication. In order to give both the scientific and animal welfare communities opportunity to express their views to the ILAR Guide Revision Committee, the Academy has agreed to hold three public hearings on this subject. One hearing will be on the East Coast, one in the Midwest, and the third one on the West Coast. The first hearing will be held May 17, 1983, in the Academy's auditorium, 2101 Constitution Avenue, Washington, D.C.

INDEXING THE BRSG ELIGIBILITY THRESHOLD

Question: Doctor, in the report submitted to this Committee regarding changing the "Biomedical Research Support Grant (BRSG) eligibility threshold," you recommended indexing the threshold at .025% of the total NIH appropriation for research grants. What is the rationale for this particular index?

Answer: The index of 0.025 percent was first utilized by the former Director of NIH, Dr. James A. Shannon, in 1968 as a numerical measure of research grants activity that would be used to establish the qualifying or eligibility level for any given institution engaged in biomedical research funded by the NIH to receive a BRSG award. This "indexed" amount was similar in dollar size to the threshold level of five times the cost of an average research project grant (direct plus indirect costs) originally used when the BRSG Program was initiated in 1962.

Question: If the Congress were to accept your proposal, each time we added money for research grants the threshold would increase; and thus we would be eliminating from the "BRSG" program the smaller institutions in our states. Is that correct?

Answer: The threshold would rise or fall in relation to the total pool of available NIH research grants. The eligibility of any given institution would continue to be determined on the basis of how successful they were in competing in the dual peer review system for the research grant funds awarded by the various institutes and research agencies of the Public Health Service. Inflation, rather than an increase in the size of the research activity, has resulted in some smaller institutions becoming eligible for BRSG grants. This would not have occurred if the eligibility threshold had been regularly raised to offset inflation. Some smaller institutions that have qualified for support as a result of inflation rather than a heavy involvement in research would not meet the new threshold of research activity.

IMPACT OF THRESHOLD CHANGE ON SMALLER INSTITUTIONS

Question: We believe those Biomedical Research Support Grants are important to the research program of the smaller institutions. Are you trying to give the Congress an incentive for not adding money to the total NIH appropriation for research grants?

Answer: The proposed change in the eligibility threshold was made solely so that the Program would be in compliance with its original (1960) authorization language. House Report No. 86-2174, which accompanied the Bill establishing these grants-in-aid stated: "Institutional research grants, in order to be effective, must be available on an assured, continuing basis and should be related to

the size of the research grants programs of the NIH at the participating institutions." These funds are valuable to all institutions, but are better leveraged in institutions with the threshold activity established to carry out the intent of the authorization.

Question: Doctor, it is our opinion that good research is conducted at the smaller institutions, as well as at the "larger" institutions; thus their need for these "BRSG" grants is as important to them as it is to the larger schools. Do you agree?

Answer: "Good" biomedical research is being carried out at all of the institutions being funded by the NIH. The need for BRSG funds to conduct such research continues to be a matter of public record. Therefore, the issue raised by the proposed change in the eligibility threshold is one of determining the allocation of these needed funds to meet the intent of the Congress that it "should be related to the size of the research grants programs of both the NIH and the participating institutions."

Question: If we were to accept this indexing proposal, it seems to us that their would eliminate from the program entire disciplines, such as nursing and pharmacy; and nearly eliminate dentistry. Is this correct?

Answer: Yes, you are essentially correct that many of the smaller nursing, pharmacy, and dental schools would be eliminated from the program. The reason this would occur is that these schools have a small research grants base, with relatively few faculty members engaged in research funded by grants from the Public Health Service.

Question: For the record, list the nursing, dental, pharmacy, and osteopathy schools that would lose "BRSG" support if you set the threshold level at $500,000 in FY 1983 and $600,000 in 1984.

Answer: It is projected that the following institutions would lose BRSG support in FY 1983 if the eligibility threshold was set at $500,000:

Schools of Nursing

University of Wisconsin Madison
Wayne State University
University of Michigan at Ann Arbor

Schools of Dentistry

University of the Pacific
University of Texas
University of Colorado
University of Illinois Medical Center
Medical University of South Carolina
University of Louisville
New York University
Indiana University-Purdue University at Indianapolis
Emory University
Oregon Health Sciences University
Temple University
University of Maryland at Baltimore
University of Florida

Case Western Reserve University
University of Pittsburgh

Schools of Pharmacy

University of Illinois Medical Center
University of Maryland at Baltimore
Washington State University
Northeastern University
University of Texas at Austin
University of Minnesota of Minneapolis-Saint Paul
University of Washington
University of Michigan at Ann Arbor
University of Kentucky

Schools of Osteopathy

Kirksville College of Osteopathic Medicine
Texas College of Osteopathic Medicine

Question: Also, for the record, list all of the other institutions that would be adversely affected at the proposed $600,000 threshold.

Answer: The following additional institutions could lose BRSG eligibility in FY 1984 if the BRSG eligibility threshold was raised to $600,000, assuming their research grants base remained unchanged from their FY 1983 level:

Schools of Medicine

Marshall University
Southern Illinois University
Oral Roberts University
Eastern Virginia Medical School
East Carolina University
Northeastern Ohio Universities College
Louisiana State Univ. Med. Ctr.-Shreveport
University of California-Riverside
University of Nevada-Reno.

Schools of Pharmacy

University of Florida
University of Iowa

Schools of Veterinary Medicine

University of Tennessee-Knoxville
Iowa State University of Science
Ohio State University
Texas Agri. and Mech. Univ-College Station

School of Optometry

University of Alabama in Birmingham

Other Academic

Clark University
North Dakota State University
Hope College
University of New Mexico-Albuquerque
Pomona College
Indiana State University
Worcester Polytechnic Institute
Teachers College
Reed College
Brooklyn College
University of Idaho
Byrn Mawr College
University of Arkansas at Fayetteville
Wright State University
Bowling Green State Univ.-Bowling Green
Brigham Young University
University of Maine at Orono
Marquette University
University of Wisconsin Milwaukee
University of Alabama in University
University of Montana
Montana State University
University of New Hampshire
Amherst College
Virginia Commonwealth University
College of Environmental Sci. & Fores.
North Texas State University
University of Rhode Island
Rutgers the State Univ. Newark
Oregon Graduate Ctr. Study and Research
Texas Tech. University
Northern Illinois University
San Diego State University
Loyola University of Chicago
Dartmouth College
Drexel University
University of Cincinnati
Ohio University Athens
Georgetown University
University of South Florida
University of Louisville
University of Minnesota
Utah State University
George Washington University

Hospitals

LDS Hospital
Children's Memorial Hospital
Mary Imogene Bassett Hospital
Magee-Women's Hospital
St. Joseph's Hospital and Medical Center
Montefiore Hospital
Mount Sinai Medical Center
Father Flanagan's Boys' Home
Presbyterian-University of PA Med. Ct.
Brigham and Women's Hospital

Mount Sinai Hospital of Cleveland
Beth Israel Medical Center
Children's Orthopedic Hospital-Med. Ctr.
Long Island Jewish-Hillside Medical
Mount Zion Hospital and Medical Center
New England Deaconess Hospital
Graduate Hospital
Philadelphia Child Guidance Clinic
St. Elizabeth's Hospital of Boston
Hospital for Special Surgery
University of Tennessee Knoxville

Research Organizations

Zoological Society of San Diego
Eastman Dental Center
American Type Culture Collection
AMC Cancer Research Center and Hospital
Christ Hospital
Lehigh University
Children's Hospital and Health Center
Indianapolis Center for Advanced Research
Texas Research Institute of Mental Science
Masonic Medical Research Laboratory
Michigan Molecular Institute
Los Angeles County USC Medical Center
Pacific Northwest Research Foundation
Blood Center of Southeastern Wisconsin
Research Triangle Institute
Cancer Research Center
North Charles Mental Health Research and Training
Allegheny-Singer Research Corporation
Institute for Med. Res. Santa Clara Co.
Peralta Cancer Research Institute
Oak Ridge Associated Universities
Papanicolaou Cancer Research Institute
J. David Gladstone Foundation
Whittier Institute for Diabetes & Endocrinology
Menninger Foundation
Monell Chemical Senses Center
Fox Chase Cancer Center
Institute for Medical Research
Long Island Research Institute
Children's Hospital National Medical
Agouron Institute

INSTITUTIONS "HEAVILY COMMITTED" TO RESEARCH

Question: In your report you use the phrase "institutions heavily committed to research" to justify the indexing of the threshold. What is your definition of "heavily committed."

Answer: The phrase "heavily committed" in the context of the BRSG Program, was first identified in the Senate Appropriation Committee's Report No. 89-1631 when the Committee indicated that" ...the primary purpose of this (BRSG) program is to provide academic institutions that are heavily committed (emphasis added for identification) to mission-oriented project research, supported by

NIH, with a small, relatively flexible fund for the development of their biomedical research in accord with institutional objectives." NIH has interpreted "institutions heavily committed to research" to mean those institutions which place a significant emphasis on, and are conducting an externally funded biomedical research activity. A heavy commitment is defined as a research activity level equivalent to five NIH research project grants or alternatively, 0.025 percent of the total NIH appropriation for research grants. Both approaches result in the same threshold.

Question: It seems to us that a small institution might be "heavily committed" to basic research at an operating level of $200,000. Moreover, the availability of "BRSG" funds is just as important to that small institution -- in order to pursue new lines of research, or to support a new young investigator -- as it would be to a large institution. Now, can you explain to the Committee why you believe these BRSG funds are not important to the small institutions?

Answer: BRSG funds are highly desirable at all types of institutions because they provide institutional flexibility and permit local decision making. Both large and small institutions have used their allocation of BRSG funds wisely and well through the years, and both have continued to express the need for, and importance of, this type of support. The proposed change in the threshold was not intended to imply that BRSG funds were not important to small institutions, but to continue to conduct the program in conformance with the intent of the legislation.

SUPPORT FOR YOUNG INVESTIGATORS

Question: If we accept your proposal, how will the small institutions fund the new young investigator or start up a new and creative line of research?

Answer: Although BRSG funds are an important means for funding new young investigators and starting new and creative lines of research, they are not the sole source of such funds. These activities are also supported by foundations, private donors, and the NIH New Investigator Research Awards supported by all institutes and the Small Research grants program now supported by the Division of Research Resources and three other Institutes.

PROTECTING THE INVESTMENT

Question: At a time when many budgets are going down, Congress has been increasing funding of the National Institutes of Health, including your Division. We are concerned that these scarce resources be carefully and effectively used and that there be no basis for criticism of your management of this money. What assurances can you give us that your Institute is making careful and effective use of the appropriations we provide you?

Answer: The Division of Research Resources has many ways it assures the effective use of the appropriations provided. Through the dual peer review system all grant applications are carefully reviewed for scientific merit and to assure compliance with Division policies, Federal policies, and matters involving ethical considerations. Advice and recommendations are sought from advisory

panels, initial review groups and the National Advisory Research Resources Council related to the review and evaluation of the scientific merit of grant applications competing for DRR support. Once an award has been made, annual Progress Reports are required to evaluate the research progress and enable staff to ensure that funds are being properly used. Site visits are conducted by Division staff to enhance program monitoring and provide the necessary scientific and administrative information necessary to effectively carry out the Division's mission. In addition, Division staff adheres to all grants management policies and directives, as well as all necessary accounting and reporting procedures as required by the Department of Health and Human Services.

Question: Aside from the peer review system, what institutional arrangements do you have that serve to deter waste, fraud, or abuse in the handling of Federal grants?

Answer: The National Institutes of Health has begun compiling information with respect to its activities on fraudulent practices such as fabrication, falsification and misrepresentation of data, failure to observe requirements for the protection of human subjects and the welfare of laboratory animals; and other practices constituting a serious breach of professional ethics or violations of terms and conditions of an award. The Division of Research Resources' main defense against waste, fraud, and abuse is a well-trained, knowledgeable staff, who are familiar with program issues and research methodologies. Our staff is on the lookout for problems and frequently communicates with grantees to seek clarification when there are questions. If suspicious circumstances are uncovered, or if such circumstances are brought to our attention by others, they are referred to the Division of Management Survey and Review, Office of the Director, National Institutes of Health, for investigation. Recently, the Department of Health and Human Services has also decided to place a statement on each Notice of Grant Award indicating a toll-free hotline which individuals can call to report misconduct. All grantee institutions have been notified of the existence of the hotline and in the future it will appear on all awards.

IMPACT OF BRSG REDUCTION

Question: The April budget proposes to cut about $24.7 million from the January request of $47.4 million for Biomedical Research Support grants. This would be a 52 percent reduction from January and a 55 percent cut from the current fiscal year 1983 level. What will be the impact of such a stiff cut on the research conducted by the approximately 500 institutions receiving funds under the program?

Answer: The Biomedical Research Support Grant Program awards funds to research institutions based on their level of PHS research grant support. These funds complement or supplement project grants by providing for pilot research, support of new investigators, centrally shared instrumentation, interim support and emergency funding. In FY 1982 BRSG funds were used to support nearly 9000 of such research activities in 516 grantee institutions. The proposed reduction in the BRS grant activity of $24,657,000 would result in a 52 percent reduction in the average size of all BRS awards. As such, 52 percent of research activities at the institutional level that are

currently supported by BRSG awards would have to find other sources of funding.

Question: How do you expect these institutions to absorb the cut you wish to impose?

Answer: Each institution will analyze its own sets of priorities in the context of its total support from all sources for biomedical research and respond accordingly. Depending upon the profile of use established for BRSG funds, some institutions may turn toward other discretionary funds such as private funds or special endowments for funding new young investigators, pilot projects, central shared facilities and resources, and emergency and interim funding needs.

Question: Your January justification makes clear that the BRS program compliments and supplements NIH's regular research grants and serves an "important need." Does your proposed cut now tell us that you do not see the BRS program as serving that "important need" that you saw in January?

Answer: In the context of all the mechanisms that NIH uses to support biomedical research, e.g., traditional research project grants, program project grants, center and resource grants, the institutional research grants of the Biomedical Research Support Programs continue to serve an "important need." However, in terms of the priorities assigned to these different mechanisms, the administration has determined that funds for the category of research project grants have the highest order of priority.

BRSG ELIGIBILITY THRESHOLD CHANGE

Question: In our fiscal 1983 Committee report we directed that you not raise the research base threshold for institutions wishing to receive assistance under the Biomedical Research Support Grants Program (BRSG). Your proposal would have increased the base from $200,000 to $500,000, knocking out schools and other research facilities that didn't meet the $500,000 standard.

We now find out you have proposed raising the threshold to $350,000 in fiscal 1983 and plan to raise it to $600,000 in fiscal 1984. What are your reasons for making this recommendation -- and we assume your plans for FY 1983 are still in the recommendation stage and are not an accomplished fact.

Answer: The eligibility threshold levels proposed for FY 1983 are still only at the recommendation stage. Since academic institutions count heavily on these awards and on receiving them in a timely fashion, we initiated procedures which allowed us to make partial awards for FY 1983, based on a $200,000 threshold, by April 1, 1983. A final installment will be made later in the fiscal year when congressional action has been taken to resolve the eligibility threshold for FY 1983.

Question: Your report says nothing about the impact of your cutoff on the nursing, dental and pharmacy schools, as well as others, that would be dropped from the program. What sorts of research that might prove promising are no longer to be supported?

Answer: Since the institutions in question use the BRSG funds for a variety of self-determined purposes, it is difficult to project before the fact what sorts of research may no longer be supported. However, examination of their latest available BRSG annual progress report from 1981 indicates that their BRSG funds had been used for the following kinds of research:

o Dentistry:
  oo Mechanical properties of tooth replacement materials
  oo The formation and control of dental plaque
  oo Bone and tooth mineralization

o Pharmacy:
  oo Stereoselectivity of drugs
  oo Neuropharmacological and behavioral study of phenylcyclidine, a street drug commonly known as "angel dust".
  oo Tissue distribution of DES

o Nursing:
  oo Sociology of self care agencies for adolescents
  oo Patient sensations related to tracheotomy
  oo Anxiety studies of birthing environments

Question: Is it your view that only the large schools with a big research base have a monopoly on good research ideas?

Answer: No specific type or size of an institution has a monopoly on "good" research ideas. The issue involved in establishing an eligibility threshold for receiving a BRSG award whether it be $100,000 in the 1960's, or $200,000 in the 1970's or an even higher eligibility threshold level in the 1980's is that of the most appropriate manner for the allocation of these funds. The NIH will respond to Congressional guidance in this matter.

GCRC BUDGET REDUCTIONS

Question: We note you plan to maintain the 74 General Clinical Research Centers, but reduce funding by $2 million. What will be the impact of this reduction, and how do you expect the Centers to make up the lost dollars?

Answer: We do plan to maintain all 74 General Clinical Research Centers in 1984 that we supported in 1983. The 1984 request includes a $4.8 million increase for the GCRC Program over the 1983 level. This reflects a 6.5 percent increase which should help to defray a portion of the inflationary costs. In 1982, the annual inflation rate for hospital care costs was approximately 12 percent. In the January budget request, the GCRC budget included a 10 percent increase for inflation. I believe the $2 million reduction you are referring to was from the January request. The GCRC Program was reduced by $2,021,000 in April, from the January budget, in order to assist with the funding of 5,000 new and competing research project grants. Since inflation rates are expected to decline in 1984, we assume that the 6.5 percent increase will be sufficient to maintain almost the same level of operations as in 1983. Some reductions may be necessary in order to absorb this reduction of $2 million. These reductions would come from the variable costs of the Centers which depend on the number and kinds of patient admissions to the Centers.

Question: To what extent was your January budget of about $80 million for the Centers based on plans to negotiate reduced awards?

Answer: The January budget of $81,412,000 for the General Clinical Research Centers was $2,021,000 higher than the revised April budget. The January budget included a 10.0 percent increase for inflation for hospital costs, which was then offset by a reduction in indirect cost payments. The inflation rate for hospital costs in 1982 was approximately 12 percent. Since the rate of inflation is expected to decline in 1984, we assumed that the 10.0 percent increase would be sufficient to maintain all 74 GCRC's at the same levels of operation as in 1983. As a result, we had no plans to negotiate reduced awards within the January budget level of $81,412,000.

DEMAND FOR CLINICAL CENTERS

Question: With hospital costs ever on the rise, there is some thought that clinical investigators may make greater use of the Centers for their work. What can you tell us about this, and wouldn't your cutback thwart such plans?

Answer: It does appear likely that many clinical investigators will make greater use of the General Clinical Research Centers for their work. There are two reasons why this will occur. First, with hospital costs rising, few investigators will be able to afford to pay these hospital care increases from funds they receive through research project grants. As a result, many clinical investigators will seek out the more economical clinical resources provided by the General Clinical Research Centers. Second, under the Administration's policy to support 5,000 competing research project grants, many of the Institutes of the NIH either reduced support or phased out several of their specialized centers in the 1984 request. Many investigators who previously relied on these specialized centers for support of their clinical activities, will instead have to rely on the General Clinical Research Centers.

Despite this anticipated increase in demand for the Centers, we expect that the 6.5 percent increase from 1983 to 1984 will be sufficient to meet the demand if we continue to impose sound management practices and begin now to plan for the increased demand. This could include such things as a shift to more outpatient research days which are more economical than inpatient days, or the implementation of policies to reduce the length of inpatient studies, or even the implementation of user fees in some cases.

ANIMAL FACILITIES IMPROVEMENTS

Question: As per our request, you have provided a report on the need for replacement, renovation and acquisition of animal facilities at biomedical research institutions. You quote a 1978 National Research Council survey indicating that many institutions need replacement and remodeling of facilities and 43 percent need additional space. How reasonable and current is this assessment?

Answer: The 43 percent additional space need is an accurate assessment and probably valid yet in 1983. However, the more urgent needs are the needs of 16 percent of nonprofit biomedical research

organizations to replace animal space now in use and the need by 38 percent of them to remodel space.

Question: Is there any way to determine the cost?

Answer: Space replacement and remodeling costs have been estimated by the National Academy of Sciences. The 1983 costs can be estimated by multiplying their figures by 1.4, the construction cost inflation factor for the past five years.

Question: Since research grants put a limit of $100,000 on the amount that may be used for alterations and renovation, do you suggest that Congress remove the limitation, or authorize a new program in the field?

Answer: In our judgement there is no need for Congressional Action on either count. Our experience has been that the limit of $100 thousand for alterations and renovations generally is satisfactory, especially when one recognizes that there are many other priorities for research grant funds. In addition, we are able to waive the ceiling on individual cases given adequate justification; and, should further experience indicate that the $100 thousand limit is too low as a general across-the-board measure, we have authority to alter the policy. With respect to authorization of a new program, we believe such an initiative cannot realistically be accommodated within the overall economic restraints that must apply to funding for biomedical research.

Question: How important is it that animal research facilities be updated and improved--and additional space be added?

Answer: It is important that animal research facilities be updated and improved; additional space could subsequently be considered. Additional space should not be confused with replacement space, the latter of which is needed for so many facilities.

Many research animals are housed in facilities built in the 1950s and early 1960s when biomedical research was expanding and funds were readily available for construction. These buildings have had heavy use, constant cleaning, and have been subject to weekly, if not daily, stress from movable equipment. More modern housing systems and more economical ventilation and cleaning systems could be placed in renovated facilities or incorporated in new ones, thus improving animal health and reducing maintenance costs.

Research animals which are being held on longer term studies of such topics as aging, and chronic and degenerative diseases are very valuable, and it is important that this investment be protected. Additionally, there is increasing public concern over the welfare of laboratory animals and the need to improve animal facilities.

Questions Submitted by Senator William Proxmire

PRIMATE CENTERS EVALUATION

Question: Dr. Pickett, within the past few years NIH has had its primate centers evaluated on two occasions by panels of independent research scientists and serious questions were raised each time.

According to information presented to my staff, the panels criticized the "cafeteria" approach by which any funded research can be undertaken at any center and noted the absence of any "quality control mechanism" for core scientists, who tended to stay on indefinitely once they were hired. The panel suggested that a stringent review be instituted for core researchers and that core salaries be limited. What has the Division done to implement the recommendations made by the evaluation panels?

Answer: All recommendations of the two evaluations cited were carefully considered by DRR staff, with the advice of the Subcommittee On Primate Research Centers of the Animal Resources Review Committee and the National Advisory Research Resources Council. Certain recommendations which were considered to be both feasible and meritorious in terms of potential for improving the Program have been implemented.

Research projects conducted within the seven Centers must receive stringent peer reviews, both within the Centers and by expert committees, which advise the funding agencies before their implementation is permitted. This policy is applied to all research projects, whether they are to be conducted by core scientists or affiliated scientists. Core staff scientists have received periodic reviews since the inception of this Program. These reviews are conducted by internal committees which advise the Center Directors on personnel matters, as well as by committees of the host academic institutions where the core staff members hold joint appointments. Unless their duties are of an administrative or professional service nature, core scientists are expected to compete for research funding from outside funding agencies. These types of administrative and peer scientific reviews are similar to those used in most academic institutions and have served the Centers well in maintaining productive staffs of high scientific quality.

Both the 1976 and 1979 evaluations recognized that the retention of productive scientists for sustained periods of time is a highly desirable goal which would enhance the stability of the Centers. A suggestion was made in the 1979 study that much greater amounts of base grant funding be made available to approximately 60 selected "core" scientists within the seven Centers. This suggestion has not been followed due to insufficient funds and a serious concern by both DRR Staff and Review Committee members that the provision of this increased funding for flexible usage could by-pass certain highly desirable elements of the peer review process. If this were to occur, the overall effect on quality and productivity of the Program could be diminished.

CORE SUPPORT IN PRIMATE CENTERS

Question: How much are you currently spending on core support?

Answer: All funds allocated to the Primate Research Centers Program are used for "core support". In FY 1983, the allocation for the Primate Research Centers Program is $19.3 million.

Question: How much do you propose to spend in fiscal 1984?

Answer: We estimate that $20.3 million will be made available for the Regional Primate Research Centers funding in FY 1984.

Question: I understand the panels also recommended that the number of core scientists per center should be reduced because projects undertaken by outside scientists were likely to be of higher quality than that undertaken by core personnel. Is this true?

Answer: The 1979 evaluation proposed that much larger amounts of base grant funding be provided to approximately 60 designated "core" staff scientists within the seven Centers. Under this concept, the "core" scientists would not be required to compete for project grant support from outside funding agencies. Other Center scientists of more junior status would be dependent on project grant support from outside sources on a competitive basis. This proposal was not followed due to fiscal constraints and because of a serious concern by DRR Staff and its Review Committee that the increased, flexible funding accorded to "core" staff scientists could by-pass highly desirable elements of the peer review process.

There is no evidence that projects undertaken by outside scientists are likely to be significantly different in quality from projects conducted by Center scientists. Both Center scientists and outside scientists must compete on a national basis for research funding. Therefore, the scientific quality of projects conducted by both groups is quite high and is essentially comparable.

Question: Have you reduced the number of core scientists accordingly? If not, why not?

Answer: At the discretion of the individual Centers a total reduction of approximately 12 full-time equivalent core staff positions have been made since 1979.

Question: How many core scientists does each center presently have?

Answer: The number of doctoral-level, core staff scientists at a given Center is variable. On a full-time equivalent basis, the total number within the seven Centers in 1982 was 105 FTE positions. A distribution of the full-time equivalent core staff supported by DRR and other funding agencies, by center, for 1982 is shown below:

Primate Center	1982 FTE's Core Staff
Oregon	28
Delta	15
Yerkes	16
Washington	11
Wisconsin	14
New England	10
California	11
Total	105

Question: How does that compare with the number of core scientists each center had in 1979, when the last evaluation was conducted?

Answer: In FY 1979, the total full-time equivalents (FTE) of doctoral-level, core staff scientists within the seven Centers was 119. In FY 1982, the total full-time equivalents (FTE) or doctoral-level, core staff scientists was 105, a net decrease of 14 FTE positions.

PRIMATE UTILIZATION AUTHORITY

Question: One panel recommended the establishment of a Primate Utilization Authority under the National Research Council. Such a group would estimate future primate needs; identify inappropriate users; and decide what species should be bred. Has such an authority been established?

Answer: Although the evaluation study suggested such an authority, this suggestion has not been followed. It was concluded that an authority of this nature would essentially duplicate the functions of the existing Interagency Primate Steering Committee.

SUBSTITUTES FOR PRIMATES

Question: It was also recommended that you "relieve some of the demands on the current primate supply by supporting research to seek suitable substitutes for primates". Have you funded any work in this area?

Answer: Many in vitro procedures (cell cultures, hormone assays, etc.) are commonly used in all seven Centers. The Division has not yet funded research to seek additional substitutes for primates. The Centers have made considerable progress in developing conservation methods and reducing the numbers of primates used. According to a recent analysis by the Primate Information Center, University of Washington, the percent of scientific articles on in vitro studies increased eight-fold during the period of 1973 - 1982. The Primate Research Centers' publications were included in that analysis.

DRR EVALUATION OF PRIMATE CENTERS

Question: My office has received a substantial amount of mail from animal welfare groups concerning this problem and, among other things, the groups are requesting congressional oversight of the Centers. What mechanisms do you have in place to evaluate these Centers?

Answer: The most important mechanisms employed in the continuous evaluation of the seven Centers are oversight and on-site reviews by the Subcommittee On Primate Research Centers of the Animal Resources Review Committee; the National Advisory Research Resources Council; categorical peer review committees, which serve in an advisory capacity to the various biomedical research funding agencies; advisory committees within the Centers; and regulatory agencies (i.e., USDA and FDA Good Laboratory Practice Act).

Question: Given the fact that the centers are reviewed at the end of every five years and none have been closed in the twenty years of their existence, I take it that you are satisfied with their operations. Is that correct?

Answer: The Division of Research Resources and the National Advisory Research Resources Council have continuously assessed the Centers and found them to be of high quality, productive and at the forefront of many areas of human health-related research which requires the use of nonhuman primates. The Centers were initiated over 20 years ago as a stable, long-term, national program. As such, they continue to be a very valuable national resource.

BREEDING OF TAMARINS

Question: I understand that one center had such a high mortality rate that the government terminated its breeding contract in 1981, taking the survivors elsewhere. Are you familiar with this?

Answer: We are aware of the fact that there was a rather high mortality rate in a breeding colony of tamarins (marmosets) at a Primate Research Center in 1978-79. The majority of these deaths were due to an epidemic of measles in the colony, which occurred despite excellent husbandry methods and the best efforts of a highly competent and experienced veterinary staff. After full discussions of the many problems encountered in breeding this very fastidious primate, the center and the funding agency concluded the project by mutual agreement. Domestic breeding efforts for this species, which is an extremely valuable model for studies on human infectious hepatitis, have not been successful in any laboratory to date. This is true of breeding efforts with this species, even in its country of origin (Peru).

ORANGUTANS AT PRIMATE CENTERS

Question: It was also reported to my staff that another center presently had thirty orangutans which it purchased a few years ago, in spite of the fact that this is in violation of Federal law. Is this correct?

Answer: The information referred to in this question is not correct.

Question: Do you know anything about this?

Answer: The Yerkes Regional Primate Research Center currently has 35 orangutans in its colony. Fourteen of these orangutans were wild-born and 21 were captive-born at the Yerkes Center. All wild-born orangutans were legally acquired during the period of 1963-65. These acquisitions were made eight to ten years prior to the passage of the Endangered Species Act of December 28, 1973 and the Convention on International Trade of Endangered Species in Fauna and Flora (CITES) of July 1, 1975.

FUNDING FOR THE PRIMATE CENTERS

Question: Please provide for the record a detailed breakdown of each center's operating expenses and other sources of funding. The justifications make no mention of this data. We want to know how much each center received last year -- is receiving this year -- and would receive under the proposed fiscal 1984 budget. Please also include any extramural grants or contracts it receives from other Federal agencies; and any private funding.

Answer: Budget information for the seven Primate Research Centers is displayed for FY 1982 (actual), FY 1983 (estimated), and FY 1984 (estimated) on the following page. Total federal and private funding is also shown for these years.

GORILLA SUPPLY AT PRIMATE CENTERS

Question: I understand that one center is presently using 15 gorillas in medical or behavioral research. It's been reported that neither the center authorities nor the overall director of the Primate Centers at the Division will identify the supplier of those animals. If this is true, why not?

Answer: The Yerkes Regional Primate Research Center is the only Center that has gorillas and currently has a colony of 20 gorillas. It is understood that ten of these gorillas were wild-born and ten were captive-born at the Center. All wild-born gorillas were acquired during the period of 1963-65. Records, if still maintained, related to the acquisition of wild-caught gorillas nearly 20 years ago, would be in the custody of the Center itself. Any records that might have been maintained by DRR related to the acquisition have been disposed of, according to Department policy.

Question: It's not against any Federal law, is it? Please provide this information for the record.

Answer: No Federal laws were violated in the acquisition of wild-born gorillas during the period of 1963-65. The purchase of these gorillas substantially pre-dates both the Endangered Species Act of December 28, 1973 and the Convention on International Trade of Endangered Species in Fauna and Flora (CITES) of July 1, 1975.

VISITORS TO PRIMATE CENTERS

Question: One other question, Dr. Pickett -- is it true that one center has refused admittance to members from the local animal welfare community but opens its doors for visiting scientists from the Soviet Union? According to my information, even scientists attending a recent International Primatological Society conference were not allowed to see any research monkeys and had all cameras confiscated before entering the center.

Answer: The Primate Research Centers are non-federal laboratories which are associated with academic institutions. Accordingly, all administrative policies concerning admittance of visitors to these research establishments are established and implemented by the Centers and their respective host academic institutions. It is our understanding that tours of the Centers have been scheduled for scientific and educational groups. Such tours might include scientists from any country. For example, it is known that four tours were scheduled for valid registrants at the International Primatological Society (IPS) Conference which was held in Atlanta, Georgia in August 1982. This Conference included registrants from over 20 countries. The IPS tours permitted observation of large numbers of research animals, primates in the nursery area, and photographs of laboratory research. It has been a long-standing policy of the Yerkes Center that cameras of any visitors are not permitted within the facility. Past experience has

ANIMAL RESOURCES BRANCH
DIVISION OF RESEARCH RESOURCES

Primate Center Program

Primate Center	FY 1982 ARB Support 1/	FY 1982 Other Support 2/	FY 1982 Total Support	FY 1983 ARB Support 2/	FY 1983 Other Support 2/	FY 1983 Total Support	FY 1984 ARB Support 2/	FY 1984 Other Support 2/	FY 1984 Total Support
Oregon Med Res Fdn of Oregon	3,504,063	2,076,984	5,581,047	3,671,374	2,195,071	5,866,445	3,875,857	2,304,825	6,180,682
Delta Tulane Univ	2,247,468	1,298,779	3,546,247	2,349,448	1,185,996	3,535,444	2,470,327	1,221,576	3,691,903
Yerkes Emory Univ	2,472,269	1,138,964	3,611,233	2,584,200	1,377,854	3,962,054	2,724,937	1,446,747	4,171,684
Washington Univ of Washington	3,067,474	1,503,380	4,570,854	3,205,717	1,608,733	4,814,450	3,393,547	1,689,170	5,082,717
Wisconsin Univ of Wisconsin	2,394,561	878,965	3,273,526	2,503,384	197,163	2,700,547	2,635,927	600,000	3,235,927
New England Harvard Med School	2,415,720	932,610	3,348,330	2,526,475	1,720,757	4,247,232	2,660,767	1,806,795	4,467,562
California Univ of California	2,297,945	1,300,957	3,598,902	2,401,402	1,536,399	3,937,801	2,538,638	1,613,219	4,151,857
TOTALS	18,399,500	9,130,639	27,530,139	19,242,000	9,821,973	29,063,973	20,300,000	10,682,332	30,982,332

1/ Actual
2/ Estimated

shown that camera flashes are highly disturbing to these animals which are used chiefly in non-invasive biobehavioral experiments.

Question: What do you intend to do about this?

Answer: We will relate these concerns to the Primate Centers for their consideration.

JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY IN THE HEALTH SCIENCES

STATEMENT OF DR. MARK BEAUBIEN, ACTING DIRECTOR

ACCOMPANIED BY:

DR. CORALIE FARLEE, ASSISTANT DIRECTOR, PROGRAM OPERATIONS
DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH
H. RICHARD MILLER, ASSISTANT DIRECTOR FOR BUDGET, DIVISION OF FINANCIAL MANAGEMENT, NATIONAL INSTITUTES OF HEALTH
ANTHONY ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

BUDGET REQUEST

Senator WEICKER. Next, we will hear from the John E. Fogarty International Center for Advanced Study in the Health Sciences. Fogarty is NIH's link with biomedical research on an international scale.

The budget request for the Fogarty Center is $9.1 million, which is $2.3 million below the January budget and is also below both the fiscal year 1983 and fiscal year 1982 appropriations levels.

Fogarty also acts as a channel for the annual appropriation to the Gorgas Memorial Institute, which has been doing research on tropical diseases through its laboratory in Panama since the 1920's.

And the revised budget request proposes no further funds for Gorgas.

Here to testify on behalf of the Fogarty budget is Acting Director Mark Beaubien.

Welcome, Dr. Beaubien, and please proceed.

Dr. BEAUBIEN. Thank you very much, Mr. Chairman.

I would like to introduce my colleague, Dr. Coralie Farlee, who is our Assistant Director for Program Operations.

I do have a prepared original statement.

SUMMARY OF FOGARTY INTERNATIONAL CENTER'S PROGRAMS

Senator WEICKER. We will put that in the record.

Dr. BEAUBIEN. But I will give you a brief summary of that.

Thank you.

In recognition of the vital importance of international interaction in seeking the solution to health and disease problems of the American people, the John E. Fogarty International Center was established as a component of the National Institutes of Health.

In recent years, we have witnessed accelerated progress in the understanding of disease processes and the development of sophisticated tech-

nologies that are making deep inroads in previously an intractable problem—reducing the prevalence of diseases and offering new hope.

This progress has not been accomplished in secrecy and isolation within our boundaries. International cooperation toward making continued rapid progress remains an essential ingredient.

The funds we are requesting for the Fogarty International Center for fiscal year 1984 will permit us to maintain the essential linkages which NIH has with the international research community and to foster studies of important issues and scientific topics that are enhanced by an international perspective.

Foremost in our consideration in the allocation of our resources is the benefits that are accrued to the American people by supporting the accomplishment of the mission of NIH as a whole and the individual missions of the other components of NIH through international cooperation in research.

The relatively small magnitude of these funds is not, however, a measure of the amount of interaction—international interaction—that ultimately results. Through the mechanisms we foster and support, scientist to scientist and laboratory to laboratory collaboration makes it possible for the United States to draw on special expertise, resources, and environmental conditions, wherever they may exist.

In maintaining the worldwide leadership of NIH, our perspectives are not, however, entirely parochial. We are pleased that what we can do for the American people also benefits health on a global scale. And we are not unmindful of the much greater burden of preventable disease that still plagues many societies on Earth.

We are privileged in the health sciences to be able to serve these ends concurrently. I have heard many of the institute Directors speak earlier of a number of research advances made over the past few years. I don't think there are probably any of these advances which have not been made without some international connection, either directly between our institutes with international colleagues, or somewhere in the development process of those research advances.

The Fogarty International Center, as I have mentioned, does make a particular point and has a particular mission of fostering these linkages—catalyzing linkages—between our U.S. scientists and foreign scientists.

The Fogarty International Center operates and carries out its mission in two general, broad areas of activity, one of which is its international cooperation and coordinating role, maintaining liaison with respect to international agreements and other mechanisms, and fostering exchange.

And the other major element of the Fogarty International Center's operation is its advanced studies programs. In these programs individual scientists, whether Americans abroad or foreign scientists in this country, focus on particular research topics. Other studies that the Center itself undertakes are concerned with broad biomedical research topics.

You have posed some questions to other institutes' witnesses which I will respond to.

REDUCTIONS IN FOGARTY INTERNATIONAL CENTER'S BUDGET

Senator WEICKER. Do they really relate to you?

Dr. BEAUBIEN. Not directly since we are not a research project-granting organization. They do impact to some extent in that we have had some reduction over the original proposed budget as a result of the current revision, something on the order of about $500,000 in fellowships, about 5 percent of our own program.

And I am also speaking of a $1,899,000 reduction for the Gorgas Memorial Institute, which is not really a program of the Fogarty International Center per se, although we are the conduit for those core funds that do support the Gorgas Memorial Institute.

So the revision has reduced us to some extent, but I still feel that we will be able to maintain our programs actively and viably.

Senator WEICKER. Right.

Dr. BEAUBIEN. It does terminate, of course, the support for the Gorgas Memorial Institute.

Senator WEICKER. In other words, Gorgas is one of the prices you pay for the additional $500,000.

Dr. BEAUBIEN. In a sense, yes.

GORGAS MEMORIAL INSTITUTE

Senator WEICKER. Why the elimination of Gorgas?

Dr. BEAUBIEN. Well, that decision was necessarily made at a higher level than the Fogarty International Center. In our perspective, of course, we perhaps might view it a little differently, but certainly that decision had to be based upon the larger policy and priority considerations that you have heard expressed earlier.

So that that decision must be viewed in that larger context.

Senator WEICKER. Was it based in any way on the inadequacy of the institute's work or fulfillment of its mission so that it has no more work to do? Were any of those factors involved?

Dr. WYNGAARDEN. Mr. Chairman, perhaps I can speak to that since this decision was made at the departmental level, not at the Fogarty level.

Senator WEICKER. OK.

Dr. WYNGAARDEN. I did participate in those discussions and the ultimate decision. We believe it was appropriate to generate the funds needed for the 5,000 grants, primarily because the award to the Gorgas Memorial Institute is one that is essentially passive. It does not go through the peer review system at the NIH.

In addition, the original plan for the Gorgas Memorial Institute, dating from the 1920's, envisioned support from Latin American countries on whose health problems the laboratory primarily concentrates. That has never materialized. The support from Panama is limited to about $10,000 of direct resources at this time.

In addition, there are other mechanisms for funding some of the work at the Gorgas Memorial Laboratory; it currently receives about $250,000 to $300,000 in NIH peer review grant awards.

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For those reasons, we felt that this should be one of the centers whose funds could be shifted.

Senator WEICKER. I have a letter from the Institute's President that I will include in the record at this time.

[The information follows:]

LETTER FROM LEON JACOBS, PH. D., PRESIDENT, GORGAS MEMORIAL INSTITUTE OF TROPICAL AND PREVENTIVE MEDICINE, INC.

APRIL 12, 1983.

Hon. LOWELL P. WEICKER, JR.,
Chairman, Labor-HHS-Education Appropriations Subcommittee,
1108 Dirksen Office Building, Washington, D.C.

DEAR SENATOR WEICKER: It has come to our attention, belatedly, that the funding for core support of the Gorgas Memorial Laboratory (GML) in Panama has been deleted from the budget for the National Institutes of Health, Fogarty International Center.

This means the death of the Gorgas Memorial Laboratory.

You are undoubtedly already knowledgeable about GML. It had its origin in an initiative on the part of Panama and of the United States, to commemorate the great work of William Crawford Gorgas in the control of malaria and yellow fever while the Panama Canal was constructed.

The Panama Canal is an achievement of American engineering genius and the genius of Dr. Gorgas in disease control. You will remember that after the French gave up on the venture of connecting the Altantic and Pacific Oceans, the United States came in and did the job. I hope that you have had the opportunity to see the canal at work. It is truly as impressive as the pyramids.

Since the establishment of the Gorgas Memorial Laboratory, we have had in Panama a unique establishment for conducting research in tropical diseases and for monitoring the threat of invasion of yellow fever and other arthropod-borne infections into the United States. There is no other laboratory in Central America or Panama that has the capabilities of the Gorgas Memorial Laboratory.

GML exists on two bases. First of all, there has been core support for the laboratory, as a line item in the budget of the Fogarty International Center, National Institutes of Health. This core support is authorized by Public Law 70-350, and was administered through the Department of State and later transferred to NIH. It is now authorized up to the level of $2 million. We have never received this amount; our last appropriation was $1.8 million, and we are hoping in fiscal year 1984 to receive $1.899 million.

In addition to this core support, the GML has worked on projects funded by the United States and Panama. These projects range from the testing of antimalarial drugs to the evaluation of environmental changes attendant on the construction of large hydroelectric facilities in the country.

How does one justify core support? Sir, I must tell you that there is no institution anywhere that can exist without it. Our universities and research institutions in the United States have such bases. The research done in those institutions is added on to their other functions.

The GML has to have the core funding to maintain its staff and facilities. It is then capable of mounting research efforts to monitor and control tropical diseases which still represent threats to the health of the Americas.

Since I have assumed the presidency of the Gorgas Memorial Institute, barely 1 month ago, I have been confronted with a fiscal nightmare. Because of a decrease in the grants and contracts on which GML operates, it has been necessary to effect a reorganization of the laboratory, to make it more efficient and to put it in a more competitive stance.

We now have the prospect of additional grants and contracts to work on a variety of projects. The projects include work on the biology of the Darien Gap, at the eastern end of Panama where the isthmus joins South America, to cervical cancer and certain

leukemias, of which the high incidence in Panama has attracted the attention of National Cancer Institute scientists.

All of these activities are about to cease, because the basic funding of the laboratory has been erased from the NIH budget, in revisions which the administration has just recently submitted to your committee.

I am committed to the task of assuring that GML becomes once again, as it has been in the past, a center of excellence for research on tropical diseases.

Please use your good offices to see that GML can survive and fulfill its potential. Thank you.

Sincerely,

LEON JACOBS, PH. D.,
President.

RELATIONSHIP WITH CUBA

Senator WEICKER. But let me get to the point of both the Institute and also of the Fogarty Center. I just returned for the second time in the past several years from Cuba. My visits there are not in any way related to the rhetoric that fills the newspapers. Rather, it is to establish a continuing relationship in the area of marine sciences between Cuba and the United States.

As best as I understand it first-hand, if you go to the bottom of the Caribbean Sea floor, you have a very difficult time differentiating between the Communist fish and those that adhere to democratic principles.

But obviously, in the course of those visits, I have had occasion to observe first-hand where the emphasis is being placed insofar as that country is concerned. Since that country is impacting upon our hemisphere in a rather substantial way, I think it might be well to point out in regard to the cuts that we have before us now—the military budget aside—that the greatest emphasis that Mr. Castro has placed in his infrastructure is the moneys invested in education and science and medical science.

Much of the problem really with countries in the Caribbean and Central America, and South America, is that the men and women who are being educated in those places are all over the world, helping other nations.

Cuba will graduate this year in terms of all personnel, researchers, doctors, nurses, paramedics, et cetera, some 40,000 from the university complexes of Cuba, Santa Clara, et cetera. The investment they are making in education is awesome.

On what used to be the Isle of Pines, now called the Isle of Youth, are 60 senior high school complexes, each one of many campuses. Fifteen are indigenous to the populations of other countries. At the one that I visited, 600 Namibians students were getting their education courtesy of the Soviet Union and Cuba. They will be back to Namibia and undoubtedly become the leaders of that nation in science, education, politics, and military, whatever, with an education courtesy of the Soviet Union and Cuba.

The ultimate irony, aside from the fact that we have had two Namibian students, I think, in the last several years here in the United States

under official sponsorship with its educational complex, is perhaps that the native language of the Namibian is not Spanish, is not Soviet; it is English.

Now, the reason why I raise all this is that I obviously, as I have indicated, have very strong views on the matter of how sciences and research relate to the role our Nation plays, especially in our own hemisphere, and especially where we are so well equipped to do it.

I am not going to get into a discussion of whether we are supposed to be sending advisors or troops or weapons, and the rest of that. That is not the purpose of this subcommittee. It is not the purpose of my dialog with you in as I try to understand this budget.

What I am saying to you is that the work of the Center, the work of Gorgas, whether or not it needs a firm hand at the helm and things need to be shaped up—I have already asked counsel to get me a GAO report on Gorgas—all I know is I don't care whether Panama contributes $10,000 to it or not. I am interested in displaying throughout this hemisphere what we do best and what these people are looking for.

Let me assure you what they are looking for is exactly what Mr. Castro is providing them with at this stage of the game, which is good medical care and facilities that go along with that, and at least some hope insofar as their afflictions are concerned.

So you want to talk about money, the lack of which is going to cost you big money out there. Here is one of those areas. And I am not saying that we have it to do all over the world. But I am saying there is a specific problem right on our doorstep. And, what could be generated in terms of our knowledge to benefit these people and be the proper response to communism and whatever philosophy Mr. Castro is offering.

This is the proper response. Nobody can touch us at it. We are not doing it. And that is the reason why I want this area looked at very, very carefully because I think it is exactly the wrong time to be cutting back.

It is so frustrating, gentlemen and ladies, when you sit there in that country; you know that the people on the streets have no affinity at all for the thousands of Soviets that are on that island right now, none. They love the Americans. They have no affinity with the Soviets. There is no chemistry there at all.

You know that. You sit in your room at night, turn on the tube, and all you can get is Oriente playing Havana in baseball or some other equally heated baseball rivalry.

If you wander through the museums, in the last room, they point out the final stages of their uprising against the Spanish masterminded by Jose Marti who lived in the United States, was a great friend of the United States.

They show the final battles in murals along the walls. And then they come to that point in the museum, they point up to the flag that was made in New Orleans, that was patterned in both its style and color after the flag of the United States, and you ask yourself how in God's

name did we ever get to this point? With all these things going for it, how did we get to this point where there is no United States, there is no U.S. presence?

Now, I didn't mean to get into an in-depth discussion of our foreign policy, but I do know this: In terms of science, in terms of medicine, which is so desperately needed, the knowledge is needed, the findings are needed, the professionalism. All this is needed so desperately. For us not to offer that just shows a deep ignorance of what the problem is.

And in my small way, as best I can at this end, I just will not permit, I will not allow, my country to act in that kind of ignorance. I am no Communist, but I will tell you one thing, I think people who do the greatest disservice are those who are afraid to interact in the arenas where the conflict is taking place.

One of those areas, believe me, in the Western Hemisphere is the area of science and medicine. And, albeit with the best intentions of effort, theirs still is no match for ours.

But the feeling that you come away with is that we are not even there. It is the most frustrating feeling I have ever had in my life. We are not there.

So that is, you know, what I feel at least this aspect of the budget represents. And we will take a careful look at it.

As I say, the one thing I am not in a position to evaluate is just how much of a benefit Gorgas is and what we would expect from it in terms of quality. I would like to have further discussions with your office, Dr. Wyngaarden, and have GAO take a look at it and also a more detailed breakdown of the Center's activities, and especially those activities as they relate within this hemisphere.

Dr. WYNGAARDEN. Yes, sir.

INTERNATIONAL RESEARCH RELATIONS WITH THE WEST INDIES

Dr. BEAUBIEN. Mr. Chairman, I might just add the comment that, while we don't have formal scientific relationships with Cuba, we have this last year opened up a fellowship relationship or renewed it—it was in existence some decades ago—for the Caribbean Basin for our international research fellowships through the University of the West Indies. So we do have that new initiative.

Senator WEICKER. I hope you do. And I am not sure—as I say, it is not just the Cuban problem—it is a problem throughout the nations, which is what I am speaking for in terms of your activities. How much do you have going on aside from the University of the West Indies? Where is that located?

Dr. BEAUBIEN. Kingston, Jamaica.

Senator WEICKER. Anything else?

Dr. BEAUBIEN. Yes; we have had relationships through the NIH Division of Research Resources in instrument repair and biomedical instrumentation, through a contract with AID. We have, of course, many other relationships with Latin American countries.

Senator WEICKER. But I am interested in the Caribbean and Central America.

Dr. BEAUBIEN. Of course, Haiti is in the front pages right now with regard to that.

Senator WEICKER. Well, believe me, Haiti is always in the forefront in the sense they have the lowest per capita income. And, you know, it is easy to wander around and photograph those that are unfortunate, but that situation is just repeated actually even worse, I think, in many other nations in the globe.

All right. Well, thank you very much.

PREPARED STATEMENT AND SUBMITTED QUESTIONS

I will have further questions propounded and the staff will meet with you to try to get a more detailed understanding of what your activities are.

Dr. BEAUBIEN. Thank you.

[The information follows:]

Statement of Dr. Mark Beaubien

It is a privilege to appear before you on behalf of the John E. Fogarty International Center to report on our progress and plans. In serving as Acting Director since last July and having been associated with the Center for 11 years prior to that time, I am pleased to be able to cite continued and significant new activities that fulfill the original purposes of the Center as envisioned at the time of its establishment in 1968.

As a part of NIH, the Center shares in the fundamental mission of advancing knowledge about disease and disease processes to improve the health of the American people. At the same time, this mission serves health on a global scale. The Center has the particular responsibility among the NIH components to stimulate and enhance biomedical cooperation with the international community to achieve these ends.

While we conduct our activities along certain organizational and program lines--and I will comment on those in a few moments--there are several basic concepts that integrate and mutually reinforce these activities, which I think it helpful to mention:

- The linkages that we develop and strengthen between the American biomedical scientific community and those of other countries make it possible for us to draw upon ideas, resources, and particular environmental conditions that exist beyond our borders, now and in the future;
- The studies that we select and undertake in the biomedical sciences should be those best addressed from or enhanced by an international perspective; and
- The NIH and the United States must maintain a leadership role in the biomedical sciences as an important means of scientific achievement and advancement in the health sciences. This leadership role cannot be maintained in isolation but indeed requires international interaction.

I will summarize how some of our present and planned program activities serve these concepts.

Advanced International Studies

The role of the Center to conduct special studies of an international nature continues to receive emphasis. A key element is the Scholars-in-Residence Program, under which a small, select number of distinguished scientists are invited to the NIH to interact with our scientific staff through the conduct of research and seminars, and who in many instances form the planning nucleus for special Fogarty Center conferences. In 1982, 25 outstanding scientists from 10 countries spent from 3 to 12 months each at the NIH. These scholars--in disciplines ranging from biochemistry and molecular biology to hematology, virology, endocrinology, neurobiology, and neurophysiology--organized six major conferences in collaboration with NIH intramural scientists and regularly conducted research seminars and lecture series during their residency at NIH.

Our review of this program during the past year has confirmed that no fewer than 10 Scholars should be present at any given time for an effective exchange of ideas with each other as well as with

NIH intramural scientists, and we have planned accordingly in our budget request.

We reported to you last year on the development of our International Issues Study-Program. This program addresses issues concerning the international aspects of biomedical and behavioral research, research manpower training, and the transfer of research results to benefit international health. I am pleased to say that this activity has moved forward with considerable progress. Preparations of working groups culminated last March in a major conference that examined the potential for the control and eventual eradication of measles, a disease from which more than 1 million children die each year. This conference brought together leading experts in various aspects of this problem and reached the conclusion that present technological advances are such as to make eradication a feasible objective. The conference kindled a great deal of awareness of the opportunities and need for a concerted international effort to eliminate measles.

Two other topics in this series are under discussion by a task force and will lead to major conferences: one to be held this March will review the feasibility of eradication of poliomyelitis, and a conference early next year will focus on yaws. Following these conferences, the FIC disseminates the proceedings and recommendations throughout the Public Health Service and to other federal agencies, foreign and international organizations, and the scientific community. Another topic in this year's International Issues Study-Program is the examination of the benefits derived from the international interaction of biomedical scientists. Working groups of scientists from several countries will review recent trends in the exchange and mobility of biomedical scientists and will document accomplishments that can be attributed to such interaction. This study, again, will culminate in a conference in September bringing together research scientists and policy makers from around the world. From this activity we expect to gain insights about the types and levels of exchanges that are most effective in accelerating scientific progress as a guide to policymakers in their allocation of resources.

International Fellowships and Exchange Programs

I spoke earlier about one of the fundamental concepts underlying all our Fogarty Center activities, namely to establish channels of communication--the linkages--between American scientists and those of other countries. No programs address this objective more directly and strongly than our international fellowships and exchange programs. These programs bring together scientists of this country and those of other countries to conduct important research studies covering a wide range of biomedical disciplines. Scientists who are at early stages of their careers gain experience through international participation in research, become future leaders in their fields, and form the creative network of the future for the transmission of new ideas and research directions.

Under the International Research Fellowship Program, scientists in the formative stages of their careers conduct collaborative projects in U.S. biomedical research institutions. In 1984, 76 scientists from the 49 participating countries are expected to work with U.S. scientists at various institutions throughout the United States.

A new handbook and application guidelines will acquaint the new nominating committee in China and the reestablished committee in the West Indies, as well as those in other countries whose candidates have not previously competed successfully through the NIH peer review system, with the areas of research of importance to the NIH. Our follow-up evaluation of this program indicated that a high proportion of former fellows are now serving in advanced positions of scientific investigation or research administration in their home countries.

Under the Senior International Fellowship Program, established U.S. scientists conduct collaborative research abroad with foreign scientists in their laboratories. In 1984, 25 such awards will be made to research scientists from different parts of our country to study with scientists in a number of other countries.

The Center has pursued further efforts to expand opportunities for U.S. scientists to gain international insights through exchange and fellowship support from other sources, including other countries. In 1982, for example, we began to serve as a channel for fellowships offered by the Alexander von Humboldt Foundation in West Germany, in addition to other relationships we already have with France, Sweden, and Switzerland for this purpose. We are in the process of compiling for dissemination a directory of fellowship opportunities offered by various U.S. and foreign organizations, information which has been otherwise difficult to obtain from a single source.

International Coordination and Liaison

The Center is the focal point for the development and oversight of NIH participation in both formal and informal cooperative agreements and programs with other countries. These agreements are the framework for cooperative international research projects of the specialized Institutes of NIH. Further, the functions for international coordination and liaison provide the means to coordinate NIH international activities with the broader health policies of the Department of Health and Human Services, with foreign policy responsibilities of the Department of State, and the international scientific objectives of other elements of the Government.

The NIH is now involved in 43 agreements with 27 countries. Studies of disease prevention are prominent among these activities. As examples, the U.S.-China agreement provides for the exchange of scientists in a variety of fields including cancer, cardiovascular disease, genetics, and reproductive physiology. Research in the prevention of blindness and immunological studies will be developed as collaborative projects under a new program emphasis with India. A new agreement with Finland covers research in environmental health. Collaborative studies between scientists at NIH and in Japan include the identification of dietary factors capable of enhancing or inhibiting the mutagenic activity of substances found in food.

The FIC also provides guidance and administrative services in support of the NIH Visiting and Guest Researchers Programs. The Institutes of the NIH identify and invite foreign scientists to work with NIH scientists in particular research areas. Through these programs NIH is able to take advantage of the research talents of over 1,400 scientists from about 60 countries. These foreign scientists typically maintain continuing relationships with the NIH scientific community when they return to biomedical and health re-

search positions in their home countries. Thus, this initial collaboration, begun at NIH, results in life-long international collaboration in science and health.

An important event which occurred in this past year was the designation by the World Health Organization of the Fogarty International Center as a WHO Collaborating Center for Research and Training in Biomedicine. This is the first such designation made by WHO, and, while carrying with it no added resources or commitments on our part, it recognizes the importance that the Fogarty International Center and the National Institutes of Health can have in advancing health on a global scale. It also enhances the opportunities we have in furthering and influencing the health and scientific research objectives of WHO and the Pan American Health Organization.

This has been a brief overview of selected activities of the Fogarty International Center. To support these activities, which form an essential ingredient in the accomplishment of the mission of the NIH, we are requesting $9,189,000 for 1984.

I will be pleased to answer any questions you may have on these or other issues concerning the Center's activities.

Biography of Dr. Mark Beaubien

BEAUBIEN, Dr. Mark S.
Acting Director, Fogarty International Center, National Institutes of Health
Acting Associate Director for International Research, National Institutes of Health

October 20, 1921. Chicago, Ill. Married, three children.

Education: B.S., University of Chicago, 1944. M.D., University of Chicago, 1946.

Professional History. 1946-1947, Intern, Gorgas Hospital, Canal Zone. 1947-1950, Resident in Internal Medicine, Presbyterian Hospital, Chicago, Ill. 1950-1960, Practice of Internal Medicine, Michigan. 1953-1955, Capt. U.S. Army. 1960-1962, Vice President and Field Director in Indonesia, Project HOPE. Commissioned Officer, U.S. Public Health Service assignments (1962 to present): 1962-1964, Peace Corps Medical Officer in East Pakistan and Malaysia. 1964-1965, Regional Officer for NESA and FE, Peace Corps Medical Program, Washington, D.C. 1965-1967, Deputy Assistant Director for Public Health, USAID, Saigon, Vietnam. 1967-1969, Chief Malaria Advisor, USAID, Bangkok, Thailand. 1969-1971, Associate Director for Professional Resources, Office of International Health, USPHS, Washington, D.C. 1971-1973, Assistant Chief, International Cooperation and Geographic Studies Branch, Fogarty International Center, NIH. 1973-1976, Biomedical Officer, Bureau of Oceans, Environmental and Scientific Affairs, Department of State, Washington, D.C. 1976-1978, Assistant Chief, Scholars and Fellowships Program Branch, Fogarty International Center, NIH. 1978-1980, Assistant Chief, International Cooperation and Geographic Studies Branch, Fogarty International Center, NIH. 1980-1982, Assistant Chief, International Coordination and Liaison Branch, Fogarty International Center, NIH. July 1982,

to present, Acting Director, Fogarty International Center, NIH, and Acting Associate Director for International Research, NIH.

Professional Organizations. American Medical Association; Commissioned Officers Association, USPHS; Metropolitan Washington Public Health Association; Association of Military Surgeons of the U.S.

Honors, Awards. Honor Scholarship, University of Chicago, 1939-1941. USPHS Meritorious Service Medal, 1968. AID Vietnam Service Award, 1968. USPHS Commendation Medal, 1982.

Questions Submitted by the Subcommittee

PROTECTING THE INVESTMENT

Question: At a time when many budgets are going down, Congress has been increasing funding of the National Institutes of Health, including your Institute. We are concerned that these scarce resources be carefully and effectively used and that there be no basis for criticism of your management of this money.

What assurances can you give us that your Institute is making careful and effective use of the appropriations we provide you?

Answer: The FIC has a well-established system of budget allocation and expenditure review to ensure that we spend our appropriations wisely. Initial requests and subsequent allocations are based on an assessment of the relative priority of programs that compete for funds. These allocations are reviewed quarterly and adjusted, if necessary.

We have initiated a series of formal evaluation studies, utilizing Departmental set-aside funds, to provide an independent assessment of the effectiveness and benefits of our programs. A contract will be awarded in FY 1983 to examine the Senior International Fellowship Program. Planning is also underway for an evaluation of the significance of international cooperation to the advancement of the biological sciences. These studies, when complete, will complement the report of the Task Force to Assess the Mission and Functions of the Fogarty International Center. Essentially all the recommendations of that task force have been implemented by the FIC, and the document continues to be our basic blueprint for program administration. Other programs are reviewed periodically by FIC senior staff and management.

Question: Aside from the peer review system, what institutional arrangements do you have that serve to deter waste, fraud or abuse in the handling of federal funds?

Answer: Management staff of the FIC review all expenditures monthly to ensure that operating costs do not exceed previously established levels. Staff also review progress and/or final reports emanating from our fellowship and conference award programs to determine whether the scientific research objective of each award is achieved.

Staff also conduct periodic reviews of the expenditure reports from institutions (both domestic and foreign) which sponsor fellows

to insure that costs charged to the fellowship are necessary and proper. Finally, we have instituted a cost reduction program to lower overhead expenses and have achieved a reduction of 6 percent over the first 3 years of the 1980 decade compared to the last 3 years of the 1970's.

EXCHANGES WITH CHINA

Question: Your International Coordination and Liaison Program serves as a link with many biomedical research communities in foreign countries, including the People's Republic of China. What health exchanges have you had with China in the past year--and what have we gained from them?

Answer: During FY 1982 the NIH collaborated with Chinese research scientists both within and supplementary to the U.S.-P.R.C. Protocol for Cooperation in the Science and Technology of Medicine and Public Health. Under the Protocol there were exchanges of American and Chinese scientists in the areas of cancer, cardiovascular diseases, lung diseases, neurosciences, and environmental health. These visits enabled the development and exchange of data and information on research topics of mutual interest and benefit, and allowed the development and implementation of joint research activities.

A joint study on the epidemiology of cardiovascular disease and its risk factors in urban and rural populations in North and South China is being developed by NHLBI and Chinese colleagues. This study should provide valuable information on the effect of diet and lifestyle on blood lipid levels and cardiovascular disease that will improve the assessment of risk factors in the U.S. population.

A study planned by NICHD and Chinese scientists on pregnancy outcome in Shanghai County is particularly interesting because the reported incidence of low birth weight in China is considerably lower than in the United States.

Activities which supplement the formal health protocol include an NCI contract in cancer epidemiology. This subject is of particular interest to NIH because the incidence of specific-site cancers is vastly different in China, suggesting environmental and/or host determinants. It is expected that new insights into causes of cancer will be obtained from these studies. There were 53 Chinese scientists working in NIH laboratories in FY 1982. Two Neurosciences Fellowships were awarded to Chinese scientists and an FIC International Research Fellowship Nominating Committee was established in China in FY 1982.

Question: Do you regard these exchanges as valuable?

Answer: These exchanges open up additional opportunities for U.S. scientists that have previously been inaccessible to us. We consider these activities to be an important addition to efforts to advance scientific knowledge that will lead to better health for the citizens of both countries.

ADMINISTRATIVE CHANGES

Question: We understand you have made some administrative and organizational changes to sharpen the focus of Center activities. What changes were made and how will they improve your work?

Answer: We have recently completed the reorganization of the Advanced Studies Program to establish the International Studies Branch. This reorganization will now make it possible for us to mount special issues studies of international aspects of biomedical and behavioral research, research manpower training, and the transfer of research results to the solution of significant international health problems. The Scholars-in-Residence Program will continue to function in conjunction with this activity.

We have also expanded the responsibilities of the International Coordination and Liaison Program to take advantage of the opportunity of the FIC being designated, in 1982, as the WHO Collaborating Center for Research and Training in BIomedicine. Although this designation does not provide additional resources, it does provide the opportunity for closer collabortion with research organizations to other countries.

Question: What new or different initiatives will you take as a result?

Answer: This program will make it possible for the Fogarty International Center to identify international health issues that should receive the attention of particular NIH Institutes as well as other agencies.

We will also be able to invite special Scholars to head short-term study teams, which will conduct investigations in these specific issues areas.

Through our WHO Collaborating Center functions, we will also be able to relate to other countries and multilateral organizations in an important way.

PRICE FOR 5,000 GRANTS

Question: We're very interested in getting some perspective on the Administration's price for 5,000 new and competing grants since it does not request the additional funds needed for such a level. Instead, the revised budget proposes to put together an extra $140.9 million for this purpose by taking it away from other NIH activities. For example, we find that:

1. Noncompeting continuation awards would be cut $17 million.

2. Specialized and comprehensive centers would be reduced $49.2 million.

3. Biomedical research support awards would be cut by $24.7 million.

4. Targeted research would be reduced by $20.2 million.

5. There would be other cuts, including reductions in training, for an additional total of $29.8 million.

That adds up to a total of $140.9 million.

How do you view the activities proposed for reduction--as integral to the NIH program, or as separate from it or even as expendable?

Answer: Two FIC mechanisms have been affected by the revised budget request: fellowship awards, and core support for the Gorgas Memorial Institute.

The fellowship awards are considered to be integral to the NIH program as they provide for international scientist exchanges for collaborative research, thus permitting expansion of the NIH science base and more efficient use of resources. The reduction in this program will eliminate an increase of five awards in the International Research Fellowship program and three awards in the Senior International Fellowships program proposed in January but will allow the same number of awards as in 1983.

The second activity proposed for reduction is the appropriation for core support of the Gorgas Memorial Laboratory (GML) in Panama. As a private institution, GML is not subject to managerial controls by FIC, nor is the U.S. contribution subject to the regular NIH grant competitive peer-review process. Thus, it is not an integral part of the FIC/NIH, even though it is funded through the FIC appropriation.

GORGAS MEMORIAL INSTITUTE AND LABORATORY

Question: Our history books tell us that Dr. William Crawford Gorgas was the man who conquered Yellow Fever in the Panama Canal Region and thus removed one of the main obstacles to building that waterway. The Gorgas Memorial Institute, chartered in Delaware, and the Gorgas Memorial Laboratory in Panama, specializing in research on tropical diseases, were named in his honor. The Laboratory, supported mainly through annual funding from NIH, has been in operation for 55 years, but the Administration's new budget for the Institutes plans to deny it funding in fiscal 1984.

The January NIH budget had planned to give Gorgas about $1.9 million which is a miniscule amount when compared to the $4 billion NIH budget. Who was responsible for making the extraordinary decision to knock out the annual appropriation for Gorgas?

Answer: The decision to eliminate the funding for Gorgas was a joint decision resulting from discussions between NIH, PHS and the Department and reflects the high priority placed on supporting 5,000 new and competing research project grants. The Director of NIH and the Assistant Secretary for Health were particularly supportive of this approach in efforts to increase funding for new grants. We believe elimination of this budget item is appropriate because: (1) NIH support should be limited to projects that have gone through and been approved by our stringent scientific peer review process to assure the highest quality, and (2) little support has come to the Gorgas Laboratory from other

Latin American countries even though the Laboratory concentrates on disease endemic to the Region.

Question: Are you telling us that all tropical diseases have been eradicated from the region and therefore there is no longer any need to do research on them?

Answer: Tropical diseases continue to be important problems in that and other regions. They also pose hazards to areas in the United States, to immigrants, and to Americans abroad. Research is being conducted in a number of institutions here and abroad through various mechanisms. The United States should be alert to assure that significant research aspects continue to be addressed.

Question: We understand that the Minister of Panama has been very supportive of Gorgas and that the Laboratory helped to bring under control a recent outbreak of Venezuelan Equine Encephalitis. What can you tell us about this and about the Institute's role in Panama and the region?

Answer: Over the years the Laboratory has maintained a general surveillance over infectious diseases. The Laboratory did, indeed, monitor an outbreak of Venezuelan Equine Encephalitis (VEE) several years ago.

More recently (1981) an epidemic of over 700 cases of aseptic meningitis occurred in Panama City. GML scientists identified the Echo-4 virus as the causative agent and were called upon by the Minister of Health of Panama to reassure the public that this form of disease, although distressing, was essentially self-limiting and benign.

The GML was also helpful to the government of Panama in investigating the causes of an outbreak of acute hemorrhagic conjunctivitis.

Question: We are led to believe that if the NIH money is taken away the Laboratory will have to shut down. What will this do for our foreign relations in that part of the world?

Answer: Over the past years, the United States has been able to maintain a biomedical research and public health presence in the Caribbean. The GML has been an important element of this presence. We can expect that the government of Panama will probably object to the closing of this Laboratory.

Question: Public Law 70-350 authorizes a "permanent" annual appropration for the maintenance and operation of the Gorgas Memorial Laboratory. Have you consulted the Congressional authorizing committees as to whether they want to repeal that law? (The FY 1984 authorization is $2 million.)

Answer: The Authorization Committee has not yet been informed of the recent decision to eliminate funding for the Gorgas Memorial Institute. The Fogarty International Center will plan to inform the appropriate Authorization Committees of this development through Departmental channels. However, a permanent authorization does not guarantee an annual appropriation in any case.

GORGAS MEMORIAL INSTITUTE

Question: In our fiscal 1983 report, we asked whether it would be possible to obtain more participation from other Central American countries in the support of the Gorgas Memorial Institute in Panama which conducts research on tropical diseases. (The 1984 budget request is almost $1.9 million.) We understand that the State Department and the Minister of Health of Panama have joined you in examining this matter. What is the result?

Answer: The recent report submitted to the Committee covers the issue of expanding the base of support for the Gorgas Memorial Laboratory. The report indicates that the United States Government continues to be the prime source of the Laboratory's core support with approximately $1.8 million (72 percent of its budget) through the FIC/NIH appropriation, and an additional $300,000 from United States grant or contract agencies. As a result of the Committee's request to seek more participation from other countries of the region, the Fogarty International Center made contact with the Department of State and the GMI. These contacts are leading to an examination of various alternatives, including internationalization of the Laboratory; funding from private, multinational, and other organizations and foundations; and contributions from other countries of the region for support of the Laboratory. The Minister of Health of Panama (also a Director of the GMI) suggested a concept to the Assistant Secretary of Health, DHHS, whereby an international organization of regional countries, the United States, and the Pan American Health Organization might be established to administer the Laboratory. It is not yet clear whether under this concept other countries of the region and the Pan American Health Organization would be expected and able to contribute sufficient funds to the GML, or how the Laboratory would be managed by a multinational consortium. This concept will be explored by the GMI Directors, along with other support concepts.

Officials of the Department of State were asked by the FIC to consider the feasibility of government-to-government approaches to other countries of the region for support of the Laboratory. Officials of the Department of State believe that the GMI, as a private organization, should assume the responsibility for seeking funds from other countries if it so desires. The Department of State will, to the extent possible, provide assistance to the GML if they wish to adopt this course of action.

Question: What were some of the accomplishments of the Institute in the past year?

Answer: In the epidemiology program, two major epidemics were investigated: aseptic meningitis and acute hemorrhagic conjunctivitis; and two on-going projects were continued: the epidemiology of cervical cancer (possibly related to herpes simplex virus) and the study of other sexually transmitted diseases and their complications.

The microbiology program has been conducting studies of three major groups of infectious disease agents: viruses, parasites, and bacterias, including the study of insect and animal vectors which transmit the diseases to humans. The viral diseases being studied are yellow fever and Saint Louis encephalitis. The parasitic

diseases are malaria and trypanosomiasis (Chagas' disease). Chagas' disease is fairly common throughout Panama and Latin America and may lead to severe heart disease. Bacterial diseases studied are gonorrhea and campylobacter diarrhea, a newly recognized disease and an important cause of hospitalization of children in Panama.

Research in vector insects and reservoir animal hosts is also expected to discover the epidemiology of the transmission of leishmaniasis (possibly transmitted by the sandfly) and yellow fever.

The clinical sciences program conducted preclinical testing of potential antimalarial drugs and evaluated a rabies vaccine using various inoculation schedules at minimal dose levels.

The GML continued its pre- and post-doctoral training of students from various countries. In 1982, students from eight countries studied areas of malaria, virology, parasitology, bacteriology, and tropical dermatology.

INTERNATIONAL AWARDS

Question: You carry out an international program through which foreign scientists gain experience working in U.S. laboratories and senior American scientists go abroad to work there. Who gains most from this exchange--the U.S. or foreign countries?

Answer: The Fogarty International Center has two programs that provide for international scientist exchanges for collaborative research: the International Research Fellowship Program and the Senior International Fellowship Program. Both types of programs are designed with the ultimate benefit to the United States in mind, with the understanding that all countries share in increased knowledge and benefits.

The International Research Fellowship Program provides foreign scientists who are in the formative stages of their research careers the opportunity to come to the United States to conduct research with established U.S. scientists. Under this program the U.S. investigators gain from the exchange by having scientists from various countries come to their laboratories to conduct research and to engage in the exchange of ideas, thereby contributing to the overall research efforts of the laboratory. The foreign scientists gain from this experience by being in association with established U.S. scientists and being exposed to new ideas and techniques that can be used by these scientists upon return to their home countries.

The Senior International Research Fellowship Program provides established U.S. scientists with the opportunity to conduct collaborative research abroad. The recipients of these awards are most often senior investigators who are planning a sabbatical leave. These individuals gain from this experience in that they can spend fulltime conducting research and being exposed to fresh ideas and new research tools. Foreign scientists gain from the experience by having distinguished U.S. scientists working in their laboratories. Such exchanges have an advantage in that new techniques and assays can be rapidly introduced into U.S. laboratories and research successes or failures are not unnecessarily duplicated, thereby conserving valuable resources.

Thus, both the United States and the other country gains from these exchanges: the biomedical science base is expanded; collaborative projects result in efficient use of resources, often with serendipitous outcomes; and international health problems are addressed in an effective manner. The gain is not a one-way street; the total body of knowledge is expanded, and thus all parties gain during the exchange. This also provides the basis for continuing future collaborations.

Question: What practical results emerge that can be translated into the practice of medicine?

Answer: Most of the research that is performed under these two programs can be categorized as basic biomedical research. Unlike a regular research grant that is awarded for 3 or more years, International Research Fellowships are awarded for 12 months and Senior International Fellowships are awarded for 3-12 months. Thus the expectation is that, in both programs, scientists will be able to start projects that will be expanded upon return to their home laboratories and will continue the collaborations begun in the host laboratory in an effort to solve problems of mutual interest. There are several examples of research projects where practical results may be translated into the practice of medicine:

- Hybridoma technology in the treatment of colon and other cancers;
- Role of interferon in cancer treatment;
- Models of medical practice and care in other countries applicable to greater efficacy and lesser cost to U.S. taxpayers;
- Eukaryotic gene expression and pre-recognition of birth defects.

Question: What is the purpose of the "International Issues Study Program"--and is its work in the immunization field of a practical or theoretical nature? How much do you spend on this program?

Answer: The purpose of the "International Issues Study Program is to:

- Identify international health issues that should receive the attention of the categorical institutes at NIH as well as that of the Fogarty International Center;
- Address problems concerning international aspects of biomedical and behavioral research, research manpower training, and the transfer of research results to bring new knowledge to bear where it will benefit international health;
- Identify problems in the transfer of research findings internationally, and developing methods to overcome such problems;
- Formulate questions to be answered in identifying and selecting alternative programs or activities, and developing

a plan for action by the Fogarty International Center, appropriate categorical Institutes, or other federal agencies.

Specific issues currently being addressed are the potential eradication of selected infectious diseases, such as:

- o Measles (which kil's approximately one million children a year, worldwide);
- o Polio (with increasing paralytic cases in the developing world as development progresses); and
- o Yaws (a childhood disease now curable by penicillin).

Other issues in progress are:

- o Prevention of congenital rubella (which can have a devastating impact on the fetus);
- o Abuse of antibiotics (a growing problem worldwide which is leading tc resistant bacteria and diminishing effectiveness of our treasury of drugs); and
- o Role and significance of international cooperation in the biomedical sciences (the free exchange of ideas is critical to the progress of medical science, worldwide).

Our work brings together experts throughout the world who identify research directions that have both practical and basic considerations. The issues in the field of immunization involve considerations of the adaptation of vaccines to specific environmental conditions as well as the question of the extent to which further efforts should be devoted to the development of improved vaccines.

We plan to spend about $300,000 on this program in FY 1983. As a result of the recent reorganizaton to emphasize this program, we will now be able to take advantage of opportunities to select additional issues for study in FY 1984. We plan to spend about $400,000 in direct costs for this activity plus other support through the staff of the Center.

SCHOLARS-IN-RESIDENCE

Question: Last year you told us you were reviewing the Scholars-in-Residence Program to determine whether a broader range of disciplines (i.e., epidemiologists, behavior scientists) should be included. What have you finally decided to do on this?

Answer: We have briefed the Scientific Directors of NIH and have consulted leading epidemiologists and behavioral scientists at the NIH to stimulate nominations in these and other under-represented areas. We know of one nomination in the field of prevention of disability, particularly blindness, that will probably be reviewed this year for appointment in FY 1984. A recent call for nominations discussed, in particular, the underrepresentation in these areas. Subsequent announcements are planned for this spring.

This year, as a result of an effort to increase appointments in clinical disciplines, which was undertaken several years ago, five

of the Scholars who will be present this year are active in the following areas: diabetology; hematology (disorders of hemoglobin assembly such as sickle cell anemia); oncology; and neurology (Positron Emission Tomography scanning).

Question: There also were questions to be resolved on whether to provide for shorter terms for the scholars and whether to make changes in the nominating procedures. What is the outcome of these deliberations?

Answer: An ad hoc panel reviewed the guidelines for Scholars' appointments. A shorter term of appointment of 10 months was recommended in keeping with the length of the typical academic year of most scholars. This has been implemented as of January 1983. The nominating procedures have been strengthened in an attempt to widen the representation of all health disciplines. This effort will continue through consultation with the scientific staff of the Institutes. The membership of the advisory panel has been expanded to include representatives from a broader range of disciplines.

NATIONAL LIBRARY OF MEDICINE

STATEMENT OF DR. MARTIN M. CUMMINGS, DIRECTOR

ACCOMPANIED BY:

DR. JAMES B. WYNGAARDEN, DIRECTOR, NIH
KENT A. SMITH, DEPUTY DIRECTOR, NLM
H. RICHARD MILLER, ASSISTANT DIRECTOR, BUDGET, DIVISION OF FINANCIAL MANAGEMENT, NIH
ANTHONY ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET, DHHS

BUDGET REQUEST

Senator WEICKER. Next, we will hear from the National Library of Medicine. Dr. Martin Cummings, the Director, is back to testify on behalf of the Library.

The budget request for the Library of Medicine is $49.6 million. This is the same as the request made in January, but is $2.5 million more than the fiscal year 1983 appropriation level.

So you may proceed, Dr. Cummings.

Dr. CUMMINGS. Thank you, Mr. Chairman.

Your National Library of Medicine is the Nation's principal resource for biomedical literature. Its collection is unrivaled in the world, contains more than 3 million books, journals, in 70 languages, and a large collection of related nonprint materials.

The National Library is charged with the responsibility of not simply acquiring and holding onto these materials, but indexing them, cataloging them, and announcing their availability to the biomedical community broadly.

Twenty years ago, the National Library of Medicine pioneered in harnessing computers in the service of medical bibliography. Today, modern communications technology has been introduced into all areas of the library services.

Literally, any health professional can access our information because it is available at his fingertips through terminals. We have computer terminals in more than 2,200 medical institutions in our country and several hundred abroad. These provide on-line access to the library's highly successful information service known as MEDLARS.

Last year, more than 2 million computer searches were performed on NLM data bases. MEDLARS is the most widely used information resource in biomedicine, and some suggest it is the most widely used data base in all of science and education.

These bibliographic services are important not only because they provide access to our own collections, but because they avert the unnecessary duplication of such bibliographic processing by others. One

example of this is our centralized cataloging, which each year saves the U.S. medical library community more than $3 million.

The efficient dissemination of medical information in this country is aided by the NLM regional medical library network. This network underwent a major reconfiguration last year, reducing the number of regional libraries from 11 to 7.

In the 15 years since the regional medical library network was formed, more than 15 million books and journal articles have been loaned, and more than 10 million computer searches have been provided for health professionals.

An important element in the success of the regional medical library network has been the grants program administered by NLM. These grants have been invaluable for improving library services and for developing resource-sharing consortia of local health science libraries.

This support has led to increased self-sufficiency to the point where 80 percent of the estimated 2 million interlibrary loans each year are now filled at the local or regional level.

We have a strong international relationship maintaining exchanges of materials with more than 90 nations. And we have 13 bilateral agreements with other nations who share in the access to our system.

The library's research component, the Lister Hill National Center, continues to develop new and improved methods for handling biomedical information. Similarly, our toxicology information program uses new technologies to organize and make available important services in the fields of toxicology, pharmacology, and environmental health.

The library's programs continue to unite modern technology with its century-old tradition of providing authoritative literature-based information for the advancement of biomedical research, education, and patient care.

I would be glad to answer any questions you may have, Mr. Chairman.

CATALOGING BACKLOG

Senator WEICKER. Thank you very much.

I notice that you are hoping to reduce your backlog of uncataloged items to about 4,000 from 18,000. If your computer system is in such great shape, why is there any backlog at all?

Dr. CUMMINGS. That backlog was reduced last year. The backlog resulted many years ago from the lien that the library had, not having sufficient staff to intellectually catalog a lot of foreign language books. But stimulated by support from this committee, that backlog has been reduced to a nominal working level.

Senator WEICKER. So there is nothing you feel that needs to be done further in terms of funding or equipment that would bring it to the point where it would stay current?

Dr. CUMMINGS. No; I think what we have to do is hold onto the very good people who are required to actually read the text and then put the information, the cataloging, and indexing information into the computer.

We are not restricted by technology there. It has been the human labor-intensive effort that has been the lien on the library over decades.

NEW LEGISLATION

Senator WEICKER. You are asking us to approve bill language to permit you to use funds received in payment for certain services provided to the private sector to offset general costs of operating the library. The payments currently go to the Treasury.

Is that not authorizing legislation? And if so, why don't you go through the appropriate authorizing committee?

Dr. CUMMINGS. Well, in truth, Mr. Chairman, we have not asked for that special authority. We have reported to this committee each year on the revenues that we have earned from the sale of our services or from the leasing of our tapes. And those revenues, when they have been in excess, have been returned to the Treasury.

I believe that this is a technical amendment to accommodate for that budget that has been established. But perhaps Mr. Itteilag can elaborate on that.

Senator WEICKER. How about it, Mr. Itteilag? Have you got a little piece of legislation here?

Mr. ITTEILAG. No, we don't, Mr. Chairman.

I don't believe legislation is necessary for this. In other words, the money is being collected at this time consistent with legislative authority. This proposed language change would allow it to go to the National Library directly, and offset a small part of the appropriations which would otherwise be requested, rather than go to the Treasury.

I think it would be quite reasonable for the Appropriations Committee to accommodate us in this matter.

And I don't think that the authorizing committees would feel as if you had acted outside of your normal sphere.

Senator WEICKER. Well, you have your proposed language here and your justification, right, legislative language?

Mr. ITTEILAG. We have the language and justification. We would hope that the committee would consider it as something that could be accomplished through the appropriations process.

Senator WEICKER. No. 1, I don't like to do it.

No. 2, the authorizing committee would, I think, take offense if this were done without their OK. I would have to go through the authorizing committee.

Mr. ITTEILAG. Mr. Chairman, we would be happy to consult with the authorizing committees formally on this matter. I will also consult with counsel within the Department to see if it is authorizing-type language, and will report my findings to the subcommittee staff.

Senator WEICKER. Well, you would just love to have this little precedent, and I don't think I want to set it. This one might seem very inoffensive, but once we get into this, then there is no end to it.

You can talk with counsel on it, but it clearly to me is authorization legislation on appropriation bills. And as such, I would reject it unless by some chance I have a misreading of what is going on there.

You indicated in your presentation the great success of the regional medical libraries. If they are such a great success, why are you reducing them from 11 to 7?

Dr. CUMMINGS. We are doing that for two reasons, Mr. Chairman.

One, to reduce the overhead and the indirect cost to manage these libraries. Also new technology now makes it possible for a lesser number of regional libraries to serve a greater geographic area.

We do not believe that this reduction will have any adverse affect on the delivery of services to the various regions.

Senator WEICKER. What are the regions that are being knocked out?

Dr. CUMMINGS. Well, the regions have been consolidated as follows:

In New England, Harvard has withdrawn as a regional library and did not wish to compete for the new configuration. The New York Academy of Medicine now serves as the regional library for the Northeast with a number of subregional libraries in the various States of New England.

We ourselves served as a regional library for the Mid-Atlantic States. And we have withdrawn. This region will now be served by the University of Maryland, and it will cover the entire Southeast.

There is another consolidation that took place in the North Central States where Wayne State withdrew from the competition of being a regional library and that region is now served by the University of Illinois in Chicago.

So, in fact, we have reduced our contracted medical libraries by three. But I think the regions are relatively strong. And the services, I think, have been maintained.

Senator WEICKER. I have certainly no dispute with the regional library being in New York. I don't think that is inconvenient. And certainly New York is a great center of learning in the areas of medicine, science, research, et cetera.

I am sorry that apparently Harvard University decided to back off.

Dr. CUMMINGS. Yes; we in fact had regional libraries at Harvard, the New York Academy of Medicine, and Philadelphia College of Physicians. When we advertised for competition of the consolidated region, Harvard chose not to compete.

Senator WEICKER. Did anybody from New England compete?

Dr. CUMMINGS. The University of Connecticut. They are now involved as a resource library for the New York Academy, but they did at one time include Harvard in their proposal.

The College of Physicians in Philadelphia also withdrew.

Excuse me, the College of Physicians competed, but did not win the competition. I want to correct that statement.

PREPARED STATEMENT AND SUBMITTED QUESTIONS

Senator WEICKER. I have a few other questions which I would appreciate having you respond to for the record.

Thank you very much. I appreciate it.

Dr. CUMMINGS. Thank you.

[The information follows:]

Statement of Martin M. Cummings

What perceptive observers have been predicting has gradually occurred: computers and communications technology have transformed us from an industrial into an information society. Computers as extensions of the human brain have, in many respects, become more important than machines as extensions of human muscle. Nowhere is this more evident than in the handling of biomedical information.

The National Library of Medicine, which 20 years ago pioneered in harnessing computers in the service of medical bibliography, has since introduced modern communications technology to all areas of its responsibility. It has been applied to many library services, where a vast amount of medical bibliographic information is available, literally, at the user's fingertips. It affects our grant programs, where special emphasis has been placed on funding projects that make use of technology's potential; the Library's research and development programs, where mini-computers, microprocessors, and interactive videodisc units are now in daily experimental use; and the toxicology information program, where files of specialized bibliographic information and drug and chemical data have been created and made available. These applications not only have increased the range and quantity of information services offered by the Library, they have also greatly improved the quality and cost-effectiveness of the services.

Library Services

The National Library of Medicine is the nation's principal resource for biomedical literature. Its collection, unrivaled in the world, contains more than three million holdings in 70 languages. The NLM is charged with the responsibility to organize this vast literature through cataloging, indexing, and bibliographical listing and to publish and otherwise make this information available. Without such organization and processing, the world's literature would be inaccessible and of limited usefulness. Moreover, by performing these functions, NLM not only provides access to its own collection, but averts the repeated duplication of this processing throughout the biomedical library community. One example of this is NLM's cataloging, which saves the medical library community more than three million dollars annually in the United States alone.

The Library has developed a highly successful computerized bibliographic search and retrieval system known as MEDLARS, of which MEDLINE is the largest and most frequently used online file. MEDLARS databases are accessible at some 2,000 institutions in the U.S. In addition, there is access at a number of foreign centers and through domestic commercial vendors of information services. Each year more than two million searches are performed using MEDLINE and the other NLM online databases that supplement it. These databases, collectively, and the online network through which access is provided, constitute the world's largest scientific bibliographic retrieval system.

In 1982, the capability of the MEDLARS computer was extended to provide NLM patrons with a fully online catalog, searchable--without training or special instruction--from computer terminals placed in a public area of the Library. The online catalog has proved to be very popular with our users, and makes it possible for them to locate materials that would be difficult or time-consuming to locate using the traditional card catalog.

As a consequence of the trend toward increased data processing requirements for such services and for internal library operations, the NLM in early 1982 determined that additional computer capacity was needed to meet projected demands. A competitive procurement was conducted which resulted in the purchase--at about 40% of the commercial list price--and installation of a large multi-processor system previously used by the National Institutes of Health central computer facility. The new system doubles NLM's processing capabilities and should meet the Library's requirements well into the 1980's.

The Regional Medical Library (RML) Network, through which the nation's health-science libraries cooperate in sharing their resources, underwent a major reconfiguration in 1982. The Network which was reduced from eleven to seven Regional Medical Libraries, involves more than 100 Resource Libraries in academic medical centers, and 3,000 libraries in hospitals and other health-related institutions. The goals of the RML program remain dedicated to providing health professionals, regardless of where they are located, with timely access to reference services and to the books, journal articles, and audiovisual materials they need in carrying out their professional duties. What the new configuration will accomplish is to reduce the costs of administering the Network while maintaining the high level and quality of services that U.S. health professionals have come to expect from their libraries. In the 15 years since the Regional Medical Library Network was formed, more than 15 million books and journal articles have been loaned and 10 million computer searches have been provided for health professionals at member institutions.

Grant Programs

The Medical Library Assistance Act authorizes the NLM to award grants and contracts to strengthen the nation's health-science libraries and to increase the range and quality of information services available to health professionals. Training grants have promoted the integration of computer technology into clinical practice, teaching, and research. Research grants have supported the study of ways to improve biomedical communications; resource project grants have expedited the expansion of health-science library resources and services; and publication grants have supported the preparation of certain scientific works that, although they may not be commercially viable, are nevertheless judged to be important to the national health effort.

The results of the nation's investment in its biomedical libraries are evident. As a result of training grants, the shortage of qualified medical librarians had decreased noticeably by 1971. The training program was redirected to meet a new shortage peculiar to our information society. It concentrated on supporting training for talented individuals who would apply computer technology to information problems in the health sciences. Some 350 professionals have undergone doctoral level training in the field of computers-in-medicine. Although a modest number, it represents a cadre whose influence will be multiplied as they move into responsible positions in medical centers. Similarly, the research grants program has been redirected to emphasize investigations of computer applications in medicine.

Resource grants have been used to build library collections, institute audiovisual education services, and develop consortia of local health science libraries to improve the information resources

available to health professionals. Our support has led to increasing self-sufficiency, to the point where 80 percent of the estimated two million loans each year are filled at the local and regional level.

Research and Development

The Library's research and development component, the Lister Hill National Center for Biomedical Communications, applies computer and communications technology to handling biomedical information. One of the Center's most important projects has been to design and test an Integrated Library System that can be used by other libraries. It utilizes a minicomputer to control circulation, public catalog searching, serials check-in, patron registration, and several other functions. Much of the research and design effort has gone into making such a system easy for patrons and librarians to use. The Integrated Library System is now successfully operating in libraries of the Army (Pentagon), University of Maryland, Johns Hopkins University, Naval Research Laboratory, and Carnegie-Mellon University. Several commercial companies assist users to install the system and provide support for time-shared access to it.

Another project is investigating the potential of the optical videodisc as a medium for handling archival material in the National Library of Medicine's own collections. The Library has an estimated 30 million pages of deteriorating books and journals that it is seeking to preserve. Videodisc technology has the potential to store great amounts of published literature and make it available for rapid recall and retrieval.

Toxicology Information

The Library's Toxicology Information Program concentrates on collecting and organizing toxicological data and using computer-based retrieval systems to make this information easily accessible. TOXLINE, the first such online file developed, now contains more than 1.3 million bibliographic records. Other computerized files contain information about drugs and chemicals which may be harmful to man or his environment.

A number of the responsibilities of the Toxicology Information Program are interagency in nature. One of these, new in 1982, is to develop the Hazardous Substances Information Services for the Environmental Protection Agency. These services will provide critical information to health officials responsible for assessing the hazards from chemicals present in waste disposal sites or major accidental spills.

Summary

In the information age, NLM will continue to apply advances in modern communications technology as it seeks to carry on its century-old tradition of providing accurate bibliographic control of the world's biomedical literature. The Library's programs continue to unite innovation and technological advancements with the health sciences literature to assist biomedical research, education, and practice.

Mr. Chairman, this concludes my opening statement. I shall be pleased to answer any questions you may have.

Biography of Martin M. Cummings

NAME:
Martin Marc Cummings

POSITION:
Director, National Library of Medicine

BIRTHPLACE AND DATE:
Camden, New Jersey, September 7, 1920

EDUCATION:
B.S., Bucknell University, 1941
M.D., Duke University, 1944

HONORARY DEGREES:
Honorary Doctor of Science, Bucknell University, 1969
Honorary Doctor of Science, University of Nebraska, 1971
Honorary Doctor of Science, Emory University, 1971
Honorary Doctor of Humane Letters, Georgetown University, 1971
Honorary Doctor of Medicine, Karolinska Institute, Stockholm, Sweden, 1972
Doctor Honoris Causa, Academy of Medicine, Lodz, Poland, 1977

EXPERIENCE:
1964 to Present: Director, National Library of Medicine
1963-1964: Associate Director for Research Grants, National Institutes of Health
1961-1963: Chief, Office of International Research, National Institutes of Health
1959-1961: Professor of Microbiology and Chairman, Department of Microbiology, University of Oklahoma School of Medicine
1953-1959: Director, Research Services, Veterans Administration Central Office
1953-1959: Special Lecturer in Microbiology, George Washington University School of Medicine
1953: Associate Professor of Bacteriology, Emory University
1949-1953: Chief, Tuberculosis Research Laboratory, Veterans Administration Hospital of Atlanta
1948-1953: Instructor through Associate Professor of Medicine, Emory University
1947-1949: Director, Tuberculosis Evaluation Laboratory, Communicable Disease Center, U.S. Public Health Service
1945-1947: Assistant Resident Medicine, Boston Marine Hospital
1944-1945: Intern, Boston Marine Hospital
1942-1944: U.S. Army (ASTP)

PROFESSIONAL ASSOCIATIONS:
American Academy of Microbiology, Inc.
American Association for the Advancement of Science, Board of Directors
American Board of Microbiology
American Clinical and Climatological Association
American Federation for Clinical Research (Emeritus)
American Osler Society, President
American Society for Clinical Investigation (Emeritus)
Association of Research Libraries
Gorgas Memorial Foundation, Board of Directors
Institute of Medicine, National Academy of Sciences
Medical Library Association
Society of Sigma XI
Washington Society for the History of Medicine

SPECIAL AWARDS & HONORS:

Veterans Administration Exceptional Service Medal, 1959
DHEW Superior Service Award, 1966
DHEW Distinguished Service Award, 1968
Distinguished Alumnus Award, Duke University, 1969
Honorary Member, Alpha Omega Alpha
Honorary Fellowship, College of Physicians, Philadelphia, 1973
Rockefeller Public Service Award, 1973
Honorary Member, American Medical Writers Association, 1974
Alumnus Membership, Phi Beta Kappa, 1974
Modern Medicine Distinguished Achievement Award, 1976
Distinguished Service Award and Honorary Fellowship, College of Cardiology, 1978
Honorary Member, Academy of Medicine of the Institute of Chile, 1978
Certificate of appreciation for outstanding contributions to medical communication and to the American Medical Writers Association, 1978
John C. Leonard Award, Association for Hospital Medical Education, 1979
Harold Swanberg Distinguished Service Award, American Medical Writers Association, 1979
Fellow, American Association for the Advancement of Science, 1980
108 scientific and historical publications, co-author of textbook in the field of tuberculosis

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Questions Submitted by the Subcommittee

BACKLOG

Question: We are glad to note that you plan to reduce your backlog of uncataloged items to about 4,000 in 1983 from 18,000 in FY 1982. Do you anticipate reducing the backlog still further, or will it continue to stand at around 4,000?

Answer: NLM expects to reduce the backlog of uncataloged books to a working level of about 3,000 items by the end of FY 1984. The Cataloging Section will maintain this level as a work-in-process inventory.

Question: You indicate that coverage of medical literature on your major computer system ("MEDLINE") goes back about 18 years to 1966. Is it volume that prevents you from going backward in years at a faster rate -- or is there some other reason?

Answer: The machine readable file of indexed citations from the journal literature began in 1966. These citations have been the basis of the retrieval system (MEDLARS) since 1966; however, it was not until 1983 that all the citations were available for access online. In the early 1970's when MEDLINE (MEDLARS Online) was initiated only the citations from the most recent 2-3 years of the literature were made available online. The recent years contain the literature of most use to health professionals. Searches of the older literature were requested online, searched and printed offline and mailed

to the requestor. In 1981 NLM was able to expand online access to the literature for the period 1977 to date. This expansion of online access was very well accepted by the biomedical community and numerous requests were received for additional years online. The increased computer capacity acquired in 1982, enabled NLM to provide online access to all the machine readable files of the medical journal literature from 1966 to date. Citations to the years before 1966 are not presently being converted to a machine readable format. Health professionals may obtain references to the journal literature published before 1966 in Index Medicus, which NLM has published since 1879.

MEDLARS III

Question: MEDLARS is, of course, your computerized bibliographic search and retrieval system which contains a number of data bases. We note your continued work on the MEDLARS III software which is to automate more fully many of your internal functions such as ordering, receiving and cataloging research materials. When will MEDLARS III be fully operational--and how will it increase your efficiency?

Answer: The implementation of MEDLARS III was initiated in 1981. The major contract award for the development of the MEDLARS III software will be made by this summer. Although contractual effort will continue into FY 1985, portions of MEDLARS III will begin to be operational in FY 1984. When complete in 1985, the full system will provide:

- Automated acquisitions, cataloging, and indexing aids, now largely manual;

- Fully computerized catalog at NLM, with cataloging data available to all libraries on the online network;

- Fully automated system for online routing of requests for copies of articles, books, and audiovisuals, not essentially manual;

- Improved retrieval of computerized bibliographic information so that health researchers and practitioners can directly access the system in a "natural English" language, without the need for a trained searcher as an intermediary.

Question: Since MEDLARS III will take over many labor-intensive functions, to what extent will you save money and be able to reduce staff as a result?

Answer: The implementation of MEDLARS III in 1981 will provide tangible benefits of as much as 40 million dollars over the ten year life of the system. These benefits fall into two categories, viz. 1) Savings due to improved processing and elimination of expensive manual systems, 2) Savings to the medical library community and to health practitioners by providing improved access to NLM resources at reduced costs.

Examples of savings projected in improved internal processing over a ten year life of MEDLARS III include:

1. Closing of NLM manual card catalog eliminating expensive manual maintenance and replacing it with the current online computerized file at an estimated savings of $2.5 million.

2. Improved automated serial processing and maintenance eliminating manual checkin, subscription invoice processing, etc., at estimated savings of $700,000.

3. Automated Inventory Control with savings of $500,000.

4. Reduction of contractual services involved in keyboarding catalog records saving $350,000.

5. Reduced software maintenance resulting from a modern modularized MEDLARS III with savings of $1.4 million over the ten year life.

Examples of savings to the medical libary and health practitioner community include:

1. By providing greater and more rapid access to NLM's cataloging data, repeated duplication of the cataloging function is averted at the local level resulting in a savings to the medical library community of an estimated $4.9 million.

2. Savings to the medical library community of up to $14 million over the life of MEDLARS III by replacing manual creation and processing of up to 2 million interlibrary loan forms annually with an online automated document delivery system (DOCLINE). DOCLINE eliminates a major portion of processing required in a manual system.

NLM does not anticipate any reduction in staff as a result of MEDLARS III. The improved efficiency of NLM's internal production operations due to the new system will permit existing library staff to handle the steadily increasing demand for library and information services in a more timely fashion with improved quality.

REVISED APPROPRIATION LANGUAGE

Question: You are asking us to approve bill language to permit you to use funds received in payment for certain services provided to the private sector to offset general costs of operating the Library. The payments currently go to the Treasury. Isn't this authorizing legislation? If so, why don't you go through the appropriate authorizing Committee?

Answer: The Department has consulted with its General Counsel which agreed that language contained in the proposed FY 1984 appropriation for NLM is not authorization language and would not be subject to point of order if adopted by the Senate Appropriations Committee. According to the General Counsel, the

Library has the authority to charge fees in its authorizing statute (section 382(c) of the Public Health Service Act, 42 U.S.C. 277(c)), and thus the proposed appropriations language does not have the legal effect of investing the Library with new authority. The amounts collected by the Library as user charges are deposited in the general fund of the Treasury and are available for appropriations to the Library, if provided for in an appropriations act, to the same extent as in any other money in the general fund.

Question: What is the purpose of this new authority?

Answer: Currently NLM, through the National Technical Information Service, collects revenues from its retrieval services. This revenue is used to pay accessing costs that are not included in the NLM appropriation. Any excess between revenues and expenditures is returned to the U.S. Treasury. The new legislation would permit NLM to use these funds to offset its operating costs rather than return the collections to the Treasury.

Question: Why are you suddenly proposing to start charging for interlibrary loans, including photocopies of requested material? How much will you collect in FY 1983 and FY 1984 -- and is this action related to your request for new bill language to convert user charges to the Library's direct operations fund?

Answer: There is no relation between the proposed bill language and the Library's consideration of a plan to institute charges for interlibrary loans. NLM has been considering instituting these charges for some time.

American libraries have a tradition of free service. In recent years this approach has been undergoing a change due in part to a reduction in the financial support for libraries, a substantial increase in the amount, kinds, and costs of services provided, and a more widespread acceptance of charging for special services.

NLM instituted cost-sharing for interlibrary loan service in the Regional Medical Library Network in the late 1970's. As a result most of the larger health sciences libraries have been charging for interlibrary loans for more than five years. The Library served as the final backup resource and thus provided loans on a free basis.

NLM now believes that instituting a charge will provide both an incentive for libraries to acquire the materials their users need and to use local resources before using NLM's backup services. The National Agricultural Library and the Library of Congress charge for their loans.

When the budget justification was written, it was NLM's plan to implement charges in FY 1983. Presently, the National Library of Medicine Board of Regents will discuss the proposed changes at their meeting in May. If approved, the Library would begin to charge for interlibrary loans filled by NLM late in FY 1983 or at the commencement of FY 1984. On an annual basis,

it is estimated that $400,000-$500,000 would be collected to recover the costs associated with providing the loans of the requested materials, but not the cost of acquiring the literature.

REGIONAL MEDICAL LIBRARIES

Question: Last year you reduced the number of Regional Medical Libraries from 11 to 7. What necessitated this cutback--and has it reduced the effectiveness or impaired the services of these libraries in any way?

Answer: In FY 1982 the Medical Library Assistance Programs were reduced from 9.8 to 7.5 million dollars and in that process the funding for the Regional Medical Library Program was also curtailed. NLM believes that the relative maturity of the network plus improvements in communication technologies effected over the past 18 years permit this consolidation without detriment to the program or the services it provides to health professionals. The experience NLM has had since the beginning of the program, indicates that the larger geographical areas can be administered effectively. Funding for overhead and administrative functions is being reduced and the resultant resources are being utilized for direct services.

Question: Your library will no longer be the regional library for the Middle Atlantic States under the new arrangements. How much money will this save you -- and to what use will you put the savings?

Answer: An estimated $125,000 will be saved, in salaries and benefits. Personnel have been reassigned within NLM to meet the growing demands for basic library services. NLM will strengthen its role in planning, monitoring and providing backup services for the national Regional Medical Library Program.

Question: What is the status of the reauthorization legislation for the Medical Library Assistance Act?

Answer: Legislation authorizing funds through FY 1986 for several health programs administered by NIH, including the Medical Library Assistance Act, is pending in both houses of Congess.

The Senate proposal would extend the Medical Library Assistance program at authorization levels of $10.5, $11.025, and $11.576 million for FY 1984, FY 1985 and FY 1986, respectively. A figure for FY 1983 is also included, for $9.763 million. The bill was ordered favorably reported by the Senate Committee on Labor and Human Resources on April 13, 1983.

The House bill would extend authorization at levels of $10, $11, and $12 million in FY 1984, FY 1985 and FY 1986. The Subcommittee on Health and Environment approved the bill with amendments and referred it to the full Committee on Energy and Commerce on March 24, 1983.

PROTECTING THE INVESTMENT

Question: At a time when many budgets are going down, Congress has been increasing funding of the National Institutes of Health, including your Institute. We are concerned that these scarce resources be carefully and effectively used and that there be no basis for criticism of your management of this money. What assurances can you give us that your Institute is making careful and effective use of the appropriations we provide you?

Answer: Management of the funds appropriated to the National Library of Medicine is governed by several tiers of review on a year-round basis. In allocating its resources, NLM relies upon several outside committees for counsel and recommendations with respect to the effectiveness of both ongoing and proposed intramural and extramural activities. These bodies, whose members are drawn from a variety of disciplines, include the Board of Regents of the National Library of Medicine, the Board of Scientific Counselors, the Biomedical Library Review Committee, and a committee from the National Academy of Sciences.

Within NLM, management's most important concern in allocating resources is to provide higher quality services to the nation in a cost effective manner. It is the policy of the NLM to allocate the minimum amount of resources required to perform essential administrative functions. The highest priority for funding is given to the support of library services and products. NLM management continually reviews methods to achieve organizational efficiencies and reduce redundant management costs. One recent outcome of this process where specific administrative savings will be realized is the integration of the Lister Hill and the National Medical Audiovisual Centers. Another is the reconfiguration of the Regional Medical Library Network, reducing the number of regions from 11 to 7 to achieve administrative savings. More efficient operations are also sought through the study and application of advanced technologies for automating internal library processing functions, to handle NLM's ever-increasing workload. The MEDLARS III development project is an important effort in this direction.

Question: Aside from the Peer Review system, what institutional arrangements do you have that serve to deter waste, fraud or abuse in the handling of Federal funds?

Answer: AT NIH, the current system of prospective and retrospective reviews is excellent. Each Bureau, Institute, and Division periodically must justify its budget requests to the Director, NIH and often to higher levels of the executive Branch. These justifications are assessed with respect to the merit of what is proposed and the accomplishments to date. Similarly, each grant application and contract proposal must pass through a rigorous series of evaluations by peer reviews and staff. Progress reports of awardees are reviewed at least annually by staff in terms of both scientific accomplishments and expenditure practices. Finally, awardee institutions are subject to independent audit by the cognizant Executive Department and the General Accounting Office.

MERGER OF ACTIVITIES

Question: You indicate you have formal approval to make the National Medical Audiovisual Center a part of the Lister Hill Center for Biomedical Communications. What will this merger achieve - and what, if any, savings in money and staff are possible.

Answer: Integration of the National Medical Audiovisual Center and the Lister Hill National Center for Biomedical Communications will permit the more efficient management of research and development programs and resources. Research projects increasingly require the participation of many disciplines and technologies. Before the reorganization, these skills were found in one of the organizations and not the other limiting the effective conduct of major research activities. The reorganization will simplify project access to scarce research resources and facilities as well as focusing organizational efforts on alternative technologies and their more effective use. Specific savings are possible through the elimination of management and administrative positions and redirecting resources in the direct suport of research.

Question: A principal effort at Lister Hill is the Knowledge Base Program designed to make the latest medical research findings available to health care professionals in an easily usable format. When will this program be implemented and what areas will it cover?

Answer: The Knowledge Base Research Program is principally a research effort which experiments with methods for the computer acquisition, representation and modification of knowledge structures, to be complemented by user-friendly access. Textual and visual materials, with associated references, are the substantive content exploring coordinated knowledge structures, representations and retrieval strategies to aid in diagnosis, prognosis and treatment of disorders. The three medical domains currently being studied are human genetics (which covers more than several thousand disorders), viral hepatitis and human gastrin information. The pursuit of those basic questions of knowledge representation and retrieval will continue but the application over the broad subject of medicine will be done by others, largely the private sector.

OFFICE OF THE DIRECTOR AND BUILDINGS AND FACILITIES

STATEMENT OF CALVIN B. BALDWIN, ASSOCIATE DIRECTOR FOR ADMINISTRATION

ACCOMPANIED BY:

EDWIN D. BECKER, ASSOCIATE DIRECTOR, RESEARCH SERVICES, NIH
DR. JAMES B. WYNGAARDEN, DIRECTOR, NIH
H. RICHARD MILLER, ASSISTANT DIRECTOR, DIVISION OF FINANCIAL MANAGEMENT, NIH
ANTHONY ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET, DHHS

BUDGET REQUEST

Senator WEICKER. Last, we will hear testimony in support of the budgets of the Office of the Director and Buildings and Facilities. The funds provided through these accounts are used to run the NIH enterprise and to maintain its physical plant.

The budget request for the two accounts is almost $47 million.

Here to testify on behalf of these requests is Mr. Calvin Baldwin, Associate Director for Administration.

Mr. BALDWIN. Thank you, Mr. Chairman.

I would like to first introduce on my left Dr. Edwin Becker, who is the NIH Associate Director for Research Services. Dr. Becker's responsibilities include the areas of safety, administrative services, and our construction and engineering efforts.

Let me give you a brief summary of my opening statement. My testimony covers two appropriations that support all NIH programs.

First, the appropriation for the Office of the Director supports the Director and his staff who assist in the administration and coordination of NIH programs and in such administrative support functions as budgeting, accounting, and personnel management.

The appropriation request for 1984 for the Office of the Director is $26,720,000, an increase of $972,000 over the 1983 level. This request will maintain the Office of the Director at its current level.

The second appropriation for which I am testifying is buildings and facilities. This appropriation request of $19,900,000 provides funds for the design, construction, and repair and improvement of NIH's facilities.

Many of NIH's buildings are in need of rehabilitation and modernization. We are requesting $6,500,000 to continue the modernization of the Clinical Center, the building that houses all of the patient care and clinical research programs of the NIH at Bethesda as well as some basic research programs.

We are also requesting $8 million to continue the long-term rehabilitation of six of our 40-year-old laboratory buildings.

EFFECT OF REDUCTIONS

In answer to your question about how each appropriation has been affected by the shifting of funds to support the 5,000 grants, these two appropriations were reduced by about $3 million, a $100,000 reduction in the Office of the Director appropriation, and a reduction of about $2.9 million in the buildings and facilities appropriation.

I would like to ask Dr. Becker to tell you the effect of this reduction on the buildings and facilities appropriation.

Dr. BECKER. In trying to identify funds to help support the 5,000 grants, we decided there were three projects in the buildings and facilities appropriation request that you had seen in January which were of lower priority and could be delayed.

One of them has to do with improving access for the handicapped. This is being done in compliance with the law, but portions of the overall project have been identified for deferral to a later year. Another is an energy conservation project. And finally, regarding the modernization of the Clinical Center, $1.2 million can be deferred until a later year.

These projects will need to be done eventually, but their delay will provide some additional money this year.

Senator WEICKER. I understand the position, and this relates to your response that the cut will be from the $1 million you requested in January for removal of barriers to the handicapped in restrooms, elevators, and ramps in the NIH buildings. How much do you now intend to take away from the $1 million?

Dr. BECKER. Well, we would remove the $1 million that was planned for the barriers to the handicapped. As I indicated, that won't be permanent. We will be back at some future year to ask for its reinstatement.

Senator WEICKER. Let me make one thing very clear. I really arrived in a very good mood today, and we are just at the end of this hearing. And, by the way, to wrap it up, we will not remove the $1 million as far as the removal of barriers to the handicapped is concerned. That is obvious.

You ought to be a showcase, never mind the law. As far as I am concerned, that is just a matter that certainly ought to be of far more priority to all of you as individuals, especially with the background and knowledge that you have got.

You find that $1 million somewhere else, but I don't think we want NIH out there in front with cost savings on aids to the handicapped.

Dr. BECKER. Could I say, Mr. Chairman——

Senator WEICKER. I don't care if it is deferred; that doesn't sell me either.

Dr. BECKER. No; this is not the only thing that has been done in past years for improving access for the handicapped. There have been many

things already accomplished in terms of ramps, changes in doors, and so on.

Senator WEICKER. I am sure there has.

PREPARED STATEMENT

Dr. BECKER. These are additional things that need to be done.

Senator WEICKER. Well, let's do them, then. Your statement will be included in the record at this point.

[The statement follows:]

STATEMENT OF CALVIN B. BALDWIN, JR.

I am pleased to have the opportunity to discuss with the Committee the Office of the Director and the Buildings and Facilities appropriations of the NIH.

Office of the Director

For reasons of efficiency and economy in operations, funds for the overall direction and administration of the National Institutes of Health and for the centralized provision of a number of very essential support services are provided on a consolidated basis through the appropriation to the Office of the Director.

The appropriation is divided into two budget activities -- Program Management and Direct Operations.

The Program Management activity fund[illegible]hose components of the central administration which are prima[illegible]y responsible for the development of NIH-wide policy and procedures and the coordination of program activities. Chief among these offices is the Immediate Office of the Director, including the principal associates of the Director and staff officers who provide advice and assistance in the administration and coordination of the intramural and extramural research programs of the Bureaus, Institutes and Divisions.

Other offices supported by the Program Management portion of the appropriation provide leadership in such areas as equal opportunity, program planning and evaluation, disease prevention, medical applications of research, public and scientific communication, protection from research risks, management analysis and review, contracts and grant administration, and budget and personnel management. These offices are assisted in their efforts by numerous formal and informal advisory groups, both internal and external to the NIH, representing a wide array of viewpoints on issues central to the administration of biomedical research.

The Direct Operations activity of this appropriation provides for the administration and operation of NIH accounting functions and certain personnel activities. The accounting functions supported include financial analysis and reporting, auditing and processing of vouchers, payment of invoices, and the settlement of claims. Personnel services include counseling, training, and a wide range of similar services for approximately 15,000 employees.

Mr. Chairman, the appropriation request for 1984 for the Office of the Director is $26,720,000, an increase of $972,000 over the 1983 level of $25,748,000. The requested increase is comprised largely of mandatory items and will provide the resources necessary to maintain the Office of the Director at the current level of effort.

Buildings and Facilities

The second appropriation for which I am testifying is the Buildings and Facilities appropriation that provides funds for

the design, construction, and repair and improvement of buildings and supporting facilities for the National Institutes of Health.

The appropriation request of $19,900,000 in fiscal year 1984 is for the following:

Rehabilitation of Laboratory Buildings 2, 3, 4, 5, 7, and 8: We are requesting $8,000,000 in FY 1984 to provide for the completion of the Building 8 renovation and the design of Building 4 as part of the long-term rehabilitation effort. These laboratory buildings have been operational for approximately 40 years, and while they are structurally sound, the support systems and interior architectural features are inadequate in capacity and/or are badly deteriorated. Also, the renovated buildings will meet the requirements of the new handicapped, new life safety code requirements and energy conservation provisions.

Design funds were appropriated in FY 1981 for Building 8, and the design has been completed. Funds for the initial phase of construction were provided in the 1983 appropriation authority, and bids are being solicited. The rehabilitation of Building 8 will permit relocation of occupants now in Building 4 as a continuation of the overall modernization program.

Clinical Center Modernization: The Clinical Center, a 30-year old building, houses all the patient care and clinical research programs of the National Institutes of Health at Bethesda, as well as some of the basic research programs. In FY 1984, we are requesting $6,500,000 to continue the modernization of this building that began in 1979 and is required to meet modern fire and safety codes and to improve functional and environmental components. The program, involving more than 50 projects, is scheduled over a 10-year period so that clinical and basic research can remain operational during the entire modernization period.

Repairs and Improvements - Plant: We are requesting $1,620,000 to continue the program of major repairs and improvements to the various electrical, mechanical and structural components of the physical plants at Bethesda, Poolesville, and Baltimore, Maryland; Hamilton, Montana; Research Triangle Park, North Carolina; and other field stations for which NIH is responsible. The physical plants are quite extensive and many of the buildings and supporting facilities have been in service for four decades. There is a recurring need to provide for the repair and upgrading of physical plants.

Repairs and Improvements - Program: A funding level of $2,580,000 is also requested to continue the financing of alterations directly related to program needs. The work includes changes in physical facilities to accomodate revisions and new initiatives in research efforts.

Master Utilities: $1,200,000 is requested in FY 1984 for the planning and installation of two air conditioning chillers in the central refrigeration plant. The original seven air conditioning chillers at NIH are 30 years old. These old machines have a high potential for a major failure, and it is imperative that replacement of these machines begin. Each of the new chillers

will utilize approximately 30 percent less electricity than the old machines.

Thank you.

Biography of Calvin B. Baldwin, Jr.

BIRTHPLACE AND DATE: Radford, Virginia; December 22, 1925

PRESENT POSITION AND TITLE : Associate Director for Administration, NIH

EDUCATION

June 1943	:	Bethesda-Chevy Chase High School, Bethesda, Md.
June 1949	:	University of North Carolina, Chapel Hill, N.C.--A.B.
1949-1951	:	University of North Carolina, Chapel Hill, N.C.
1952-1953	:	American University, Washington, D.C.
1960-1961	:	Harvard University, Cambridge, Mass-M.P.A.

EXPERIENCE

1980-Present	:	Associate Director for Administration, NIH
1970-1980	:	Executive Officer, National Cancer Institute, NIH
1963-1970	:	Executive Officer, National Institute of Child Health and Human Development, NIH
1962-1963	:	Assistant Chief, Grants Management Branch, Division of Research Grants, NIH
1961-1962	:	Executive Officer, Division of General Medical Sciences, NIH
1958-1961	:	Administrative Officer, Division of General Medical Sciences, NIH
1957-1958	:	Administrative Officer, Division of Research Services, NIH
1955-1957	:	Budget Examiner, Office of the Director, National Institutes of Health
1953-1955	:	Organization and Methods Examiner, National Institutes of Health, PHS, DHEW, Bethesda, Md.
9/52-2/53	:	Civil Service Intern, Federal Security Agency, PHS
1951-1953	:	Methods Examiner, Federal Security Agency Public Health Service, Washington, D.C.
1949-1950	:	Research Assistant, Institute of Research in Social Science, Chapel Hill, N.C.

MILITARY SERVICE

1944-1946	:	Corporal, United States Army

HONORS AND OTHER SPECIAL RECOGNITION

	:	Phi Beta Kappa
	:	W.A. Jump Meritorious Award, 1960
	:	DHEW Superior Service Award, 1973

Senator WEICKER. Dr. Wyngaarden, I want to express my appreciation to you, all the Directors, and other personnel that have appeared before this committee.

And let me say that I realize that obviously, there are problems that I have that go beyond NIH and those that appear before the committee. And those are problems for me to resolve.

I just want you to know that, hopefully, you and all those that are with you are going to have long tenures here in the positions you are in. I am going to be around for 6 years. And I look forward to a very solid working relationship.

This is a learning process for me; that is the reason why I am handling these hearings personally. As I have already talked to Dr. Rall, I would hope after these hearings are over with, the next phase of my education is to visit your various facilities until I have a fair working knowledge of what this Appropriations Committee is all about.

So if the questions get a little tough, that is a blend, I would say, of maybe personal philosophy, but also a desire to know what the real needs are of NIH.

And let me just leave this thought if I might. I hear time and again not only from you and from those that accompany you, these are special times, difficult times, this is the right time, et cetera. And I only want to suggest that in terms of these kinds of endeavors, you know, we have never engaged in this kind of a philosophy as a Nation.

I don't know about the statement that this isn't the right time to house our people or feed our people or cure them from illness, et cetera: there never was a right time. I don't think there was ever a convenient time in our rather short history.

And to my way of thinking, the work that all of you represent and accomplish is a priority of this Nation. And it will never be easier to spend money for the things that you do. And so much of it, as you know, is money that has no direct success attached to it. But that is the scientific process. That is the inquiry process.

And I just cannot in good conscience trade off years in the lives in the future to accomplish pieces of politics and philosophy in the year 1983.

So in any event, we will be working with you. I want to thank you for a very complete presentation by all of you. And let's see what we can do together in the times ahead.

Dr. WYNGAARDEN. Thank you, Mr. Chairman.

Let me just say for the NIH, we appreciate the detailed interest that you have shown in our programs and the assistance that this committee has given in the past. And we look forward to this year. We would be delighted to have you visit the NIH at your convenience.

Senator WEICKER. Well, let me put it this way. I think the chances of my getting there are better than getting to the White House.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

Questions Submitted by the Subcommittee

HHS INSPECTOR GENERAL

Question: The activities of the HHS Inspector General also cover NIH. To what extent has the IG looked at your activities and what has resulted?

Answer: Two audits in recent years by the Office of Audit in the Inspector General's (IG's) office have had a significant impact on the NIH. The first was a comprehensive review of the research and development contracting activities of the National Cancer Institute (NCI) in 1978 and a follow-up review in 1980. As a result of the IG's recommendations from these reviews and NCI initiatives, the NCI has strengthened both preaward and post-award contract administration. The second review was conducted department-wide in 1980 and pertained to procedures for requesting, approving, and documenting the use of overtime. The follow-up review in 1981 resulted in the issuance of instructions by the Office of the Secretary on the internal control of overtime to which the NIH is responding by reviewing overtime usage and evaluating compliance. Reviews of lesser significance have occurred, but not all resulted in reports or recommendations.

PERSONNEL CUTBACKS

Question: We understand that you may have absorbed many of the employees cut from the Public Health Service as a result of program reductions. How extensive is this absorption?

Answer: The NIH hired 382 Public Health Service employees, ranging in grades from GS-2 to GS-15, who were potentially subject to reduction-in-force actions. In addition, the NIH hired three persons from the National Institute of Occupational Safety and Health as a result of its transfer to the Centers for Disease Control, and retroactively reinstated to an employed status five persons who were actually subjected to reduction-in-force actions, one by the Community Services Administration and four by the Public Health Service.

SHARED INSTRUMENT PROGRAM

Question: You will recall a January 31 letter in which the Committee asked that you expand the shared research instrument grant program administered by the Division of Research Resources. The purpose of our letter was to clarify the Committee's intent towards this useful program which funds the purchase and sharing of scientific instruments by facilities doing NIH research. What has been your response to our letter and how much will you put into this program in Fiscal 1983 and 1984?

Answer: In Fiscal Year 1983, the Division of Research Resources (DRR) has allocated $14 million to the Shared Instrumentation Grant (SIG) Program which will support approximately 65 instrumentation awards. DRR has also allocated an additional $1 million to provide instrumentation support specifically for institutions participating in the Minority Biomedical Research Support (MBRS) Program, an amount which should fund some 20 awards.

In Fiscal Year 1984, $14.8 million is proposed for the SIG Program, an increase of 5.5 percent; the MBRS instrumentation initiative will be maintained at the $1 million level. This information is contained in a letter which will be forthcoming to the Committee from the NIH Director.

The Shared Instrumentation Program is supported also by the National Institute of General Medical Sciences. That Institute has earmarked $1.0 million in FY 1983 and $5.0 million in FY 1984 for the program.

LAND ACQUISITION

Question: In our Fiscal 1983 Committee report, we asked that you look into the feasibility of acquiring privately owned property adjacent to the NIH campus. We understand that the 11 acres involved is the site of a convent. Is it available to be bought -- and what would be the asking price?

Answer: The parcel in question, about 11 acres, is the remaining land owned by the Sisters of the Visitation. The rest of their property, about 50 acres, was obtained by NIH in 1948 for construction of the Clinical Center. Last fall a decision was made by the Church to close the convent on the eleven-acre site, relocate the Sisters and offer the property for sale. The Sisters are desirous that the property be acquired by NIH. The asking price is $7.0 million, but our appraisals indicate a fair market value of $4.2 million.

Question: What is the relevance of the property to the long-term space needs of NIH -- and do you have a contingency plan for its use?

Answer: This land is carved out of the western edge of the NIH campus, close to the Warren G. Magnuson Clinical Center, which is the hub of research on the campus, with laboratory and clinical research housed in close proximity. It is the only parcel of land contiguous to the NIH campus that is not already heavily developed.

Of immediate interest is the convent itself, a substantially built structure of about 40,000 gross square feet. Conversion of this building to general purpose "wet" laboratories would probably not be economically feasible. However, it could readily provide a facility to bring together research programs in such areas as epidemiology and the behavioral sciences. These research programs are currently occupying space either in office buildings off campus or converted chemical laboratories. Besides reducing leasing requirements, there are practical advantages in consolidating research programs on campus. For example, epidemiologists currently in off-campus rented facilities would benefit, in terms of operational convenience and reduced costs, from being closer to the clinical investigators with whom they work on designing protocols for clinical trials.

Question: To what extent could the property be used to consolidate some of NIH's off-campus activities? (Note: NIH currently leases 460,000 square feet of office space and 18,000 square feet of laboratory space off the NIH campus.)

Answer: As indicated above, the relocation of off-campus

laboratory research would require additional construction, but other research scientists whose work does not require "wet" laboratories could be housed in the convent building. In addition, some of the larger rooms of the convent would be ideally suited to use as conference facilities that would replace such space now rented off-campus.

PROTECTING THE INVESTMENT

Question: At a time when many budgets are going down, Congress has been increasing funding of the National Institutes of Health, including your agency. We are concerned that these scarce resources be carefully and effectively used and that there be no basis for criticism of your management of this money. What assurances can you give us that your agency is making careful and effective use of the appropriations we provide you?

Answer: Annual increments to the Office of the Director (OD) appropriation consist almost entirely of amounts that cover mandatory cost increases. However, the OD strives to maximize the effectiveness of its appropriated resources through a number of administrative controls and management initiatives. The routine internal budgetary process requires the prioritization of office and division needs and the expenditure of resources according to these priorities. Administrative ceilings are established for various personnel and support categories within which expenditures must be maintained. All offices are staffed with the administrative personnel necessary to routinely monitor and review operations for conformance to plans, and to provide the necessary approvals for resource management. Within this system of controls, various initiatives are pursued to improve the overall efficiency and effectiveness of operations. One such example is the design and implementation of the NIH Administrative Data Base, a computerized information system which will convert the NIH central accounting system to a data base environment and interface it with other systems dedicated to procurement, property, and grant activities, etc. The system will reduce the large paperwork requirements now considered necessary and provide management with on-line information on daily operations. The system has already resulted in personnel savings in finance; further savings should accrue from the system as it develops and from similar efforts which accomodate modern technology to ongoing operations.

Question: Aside from the peer review system, what institutional arrangements do you have that serve to deter waste, fraud or abuse in the handling of federal funds?

Answer: The NIH's R&D contracting activities are audited by the GAO, DHHS Inspector General, the Public Health Service's Division of Grants and Contracts, DHHS' Office of Procurement, Assistance, and Logistics, and Congressional staff investigators. Outside organizations which are the recipients of NIH research and development contract awards are subject to audit by GAO, DHHS Inspector General, Defense Contract Audit Agency, their own Certified Public Accountants, and internal audit staffs.

Aside from these traditional mechanisms, the "institutional arrangements" which are integral to the research and development contracting process at NIH include:

- organizational controls in the award of R&D contracts which separate the authority to sign the contract (Contracting Officer) and the authority to obligate the funds for the contract (Fiscal Officer).

- two independent review boards that perform comprehensive presolicitation and preaward reviews of the large dollar research and development contracts awarded by the BIDs. These independent boards have full authority to instruct a BID Contracting Officer not to award a contract if it is deficient.

- internal audit surveillance over the ten research and development contracting offices at NIH. The Division of Contracts and Grants (DCG) periodically sends teams of procurement and financial analysts into each contracting office to perform a comprehensive review of all aspects of the R&D contracting function. A formal report is issued at the conclusion of the internal audit.

- a prompt and effective audit resolution function that finalizes all audit reports on outside contractors. If the NIH has been improperly charged under an R&D contract, DCG presses for full recovery of any improper payments.

- review and approval by both the NIH Contracting Officer and Scientific Project Officer of all invoices submitted by NIH and R&D contractors for payment. This review requirement precedes the actual payment and is intended to identify any improper charges to the contract on an ongoing basis.

In addition to these measures, the NIH's Division of Management Survey and Review (DMSR) conducts reviews designed to evaluate the adequacy of management control systems and safeguards on the use of Government funds, including contract and grant funds. It also oversees two other mechanisms for minimizing waste, fraud and abuse, the "Alert" and "Hotline" systems. The NIH "Alert" system was established in 1981 to provide orderly communication among NIH's 14 contract and grant units about investigations or determinations of misconduct by an individual or organization. The Hotline system was established by the DHHS Inspector General to provide easy accessibility for individuals who believe they have knowledge of waste within DHHS programs or wrongdoing by DHHS employees. Certain allegations received over the Hotline are investigated by the Inspector General's office while others are referred to the involved DHHS agency for its own investigation. DMSR has the responsibility to investigate all Hotline cases referred to NIH.

The DMSR has also been used by NIH top management as a resource for reviewing allegations about scientific misconduct. Depending on the circumstances, these cases have been handled either by DMSR, with scientific assistance, as necessary, or by ad hoc review panels, composed of scientific experts, DMSR staff, and appropriate other advisory personnel, such as a representative from the Office of the General Counsel. When deemed appropriate, these cases are also referred to the OIG for its consideration.

A number of other preventive measures have been undertaken in the area of scientific misconduct and these include: conducting

regional seminars for investigators, academic officials, and institutional review board members regarding protection of human subjects and related regulations and policies; discussing with members of NIH advisory councils and peer review groups their responsibilities related to misconduct in science; and initiating a series of random site visits to awardee institutions to assess the laboratory animal welfare assurance process. The NIH has been asked to take the lead in developing policies and procedures related to scientific misconduct for all research programs funded, conducted, or regulated by the PHS, and to include in that effort mechanisms for communication and collaboration among the PHS agencies when appropriate. An interagency committee has undertaken the development of the necessary documents, and efforts are being made to elicit the views of the research community as well.

HANDICAPPED BARRIERS

Question: Your April budget proposes to cut $2.9 million from the $22.7 million you requested in January for buildings and facilities. We understand that a portion of this cut will be from the $1 million you requested in January for removal of barriers to the handicapped in restrooms and on elevators and ramps in NIH buildings. How much do you now intend to take away from this $1 million -- and what will this do to your schedule for completing the task?

Answer: The April budget eliminates the $1.0 million that had been requested in the draft budget for removal of barriers to the handicapped. Nevertheless, we shall continue our past efforts to eliminate such barriers whenever possible, usually in conjunction with other renovations or repairs. Since Fiscal Year 1974 we have spent an estimated $815,000 on removal of barriers. This has been done with Repair and Improvement funds or as part of other projects, such as Clinical Center modernization. With the exception of the older laboratory buildings, exterior provisions for handicapped parking and accessibility are substantially completed. Other requirements to be satisfied include continued interior modifications in public spaces for mobility and convenience, and to provide audible and visual alarms in the event of fire. The $1,000,000 requested would have been earmarked for this work. Without it the initiation of projects will continue but at a reduced pace. We expect to request additional funds in future budgets.

EFFECT OF PROPOSED CUTS

Question: What effect will the other proposed cuts from the January budget have on your work relating to modernization of the Clinical Center and on energy conservation?

Answer: The deferral of $1.2 million in funds for Clinical Center modernization will result in postponing the award of certain construction contracts that otherwise might have been awarded late in Fiscal Year 1984. The impact on the pace of the modernization is not expected to be serious.

The funds that had been requested for energy conservation were targeted for a variety of relatively small projects, such as comprehensive studies of other ways in which energy can be conserved, as well as installation of storm windows and insulation

of steam lines. Deferral of the balance of these projects is not regarded as serious, but will delay the benefits in reduction of energy costs that will accrue annually.

Questions Submitted by Senator William Proxmire

UNOBLIGATED BALANCES

Question: You have had unobligated balances of over $11 million in your buildings and facilities account for each of the last three fiscal years. Why shouldn't we assume that you will have a similar unobligated balance at the end of fiscal year 1983 and cut your budget accordingly?

Answer: There are several reasons for unobligated balances in the Buildings and Facilities account at the end of each fiscal year, as follows:

- During the last three years a significant portion of the balances is attributable to the fact that we have been in the final stages of completion of three major projects--construction of the ACRF; construction of the Lister Hill Center and major upgrading of the contiguous National Library of Medicine building; and construction of the permanent facility for the National Institute of Environmental Health Sciences.

- With all construction and renovation projects there are bound to be changes that could not have been foreseen when the contract was awarded. We believe it prudent to hold aside some funds to cover such contingencies, and a portion of these funds will appear at any given time as unobligated balances.

- Because the process of advertising, securing and evaluating bids, auditing potential contractors' submissions and making awards is time-consuming, many funds that show as unobligated balances at any given time are actually committed months in advance of the formal obligation. This situation is often exacerbated near the end of the fiscal year when contract awards may be delayed because of unusual bids, bid protests, or amendments to bid documents.

- With a physical plant in Bethesda that would cost more than $1 billion to replace, there are major components of our power plant, refrigeration system and utilities complex that can undergo catastrophic failure at any time. We try to hold an adequate balance in our Repair and Improvement account to meet such contingencies.

Question: What is your current unobligated balance?

Answer: As of April 8, 1983, the unobligated balance in the Building and Facilities appropriation is $25,843,000. However, of this amount $7,897,000 has been committed to projects now in the bidding process, and an additional $12,239,000 is planned to be committed by the end of the fiscal year.

We anticipate that the unobligated and uncommitted balance will be approximately $5,707,000 at the end of Fiscal Year 1983.

SUBCOMMITTEE RECESS

Senator WEICKER. The subcommittee will recess until Thursday, April 14, at 8:30 a.m. to hear testimony from the Alcohol, Drug Abuse, and Mental Health Administration; and the Centers for Disease Control.

[Whereupon, at 11:15 a.m., Wednesday, April 13, the subcommittee was recessed, to reconvene at 8:30 a.m., Thursday, April 14.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1984

THURSDAY, APRIL 14, 1983

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, D.C.

The subcommittee met at 8:35 a.m., in room SD–116, Dirksen Senate Office Building, Hon. Warren Rudman presiding.

Present: Senators Weicker, Hatfield, Rudman, and Proxmire.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

STATEMENT OF DR. WILLIAM E. MAYER, ADMINISTRATOR

ACCOMPANIED BY:

DR. HERBERT PARDES, DIRECTOR, NATIONAL INSTITUTE OF MENTAL HEALTH

DR. WILLIAM F. DOBBS, SUPERINTENDENT, ST. ELIZABETHS HOSPITAL

DR. WILLIAM POLLIN, DIRECTOR, NATIONAL INSTITUTE ON DRUG ABUSE

ANTHONY L. ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET, HHS

PREPARED STATEMENTS

Senator RUDMAN. The committee will come to order.

This morning, we continue hearings on the budget request of the Department of Health and Human Services.

Our first witness is Dr. William E. Mayer, Administrator of the Alcohol, Drug Abuse, and Mental Health Administration, who will present the request of that agency.

You are welcome, Dr. Mayer. It is good to see you here this morning. If you would like to introduce your colleages who are with you, we can proceed to hear your statements.

The statements will be included in the record.

[The statements follow:]

Statements of William E. Mayer

It is a pleasure to appear before you to discuss the President's budget request for Federal alcoholism, drug abuse, and mental health research, research training, and prevention programs in FY 1984.

The Chairman and members of the Subcommittee are, of course, familiar with the range and complexity of problems which the programs of the Alcohol, Drug Abuse, and Mental Health Administration address. These problems are estimated to have cost our Nation $106 billion in 1977--many times the total we have invested in understanding and preventing these problems since the formation of the agency in 1949.

An estimated 10 million American adults are problem drinkers or alcoholics, and more than 3 million American teenagers abuse alcohol. Ten thousand young people are killed every year in highway accidents involving alcohol, the leading cause of death in the 16-24 age group. I personally believe that this continuing carnage should give every citizen serious pause, considering that it took only 200 deaths a year in the 1950's for the Nation to declare polio an epidemic.

Drug abuse also continues to be a serious problem in America today. Despite a welcome downward trend in the use of some drugs, including marijuana, cigarettes, and cocaine, American youth still have the highest levels of drug abuse in any industrialized Nation. Thirty-three percent of all Americans over 12 have used an illicit substance or a prescription drug for nonmedical purposes. And we still have a half million heroin users, who, in addition to their own suffering, account for a high proportion of the robberies committed on our streets and burglaries of our homes and businesses.

Serious mental health problems continue to persist among millions of Americans. Surveys estimate that between 4.5 and 7.5 million men, women, and children currently suffer from some form of depression, and up to 20 percent of our citizens will have at least one depressive episode. Fifteen percent of all people suffering from a major depression commit suicide. We also have yet to arrive at the causes of schizophrenia, which afflicts a sizeable portion of our large chronically mentally ill population.

HIGHLIGHTS OF PROGRESS

The agency's programs, with steadfast support from this Subcommittee and the Congress, are making steady progress in many directions--in expanding scientific understanding of these disorders, in improved treatment and prevention methods, and in wide dissemination of new knowledge to improve public understanding and reduce the stigma which attaches to these illnesses.

Research in the neurosciences by the National Institute of Mental Health is opening many doors to understanding mental illness and normal functioning of the brain. New biologial clues to underlying causes of schizophrenia and depression, for instance, are leading to more refined diagnostic categories and improved treatment strategies for these disorders. NIMH research also has clearly identified the neurochemical pathways involved in development of Alzheimer's disease.

Among recent advances in the area of alcoholism are findings from genetic studies that are moving us ever closer to being able to identify high risk individuals and intervene before they develop problems. This year NIAAA-supported scientists clearly demonstrated two distinct inheritable forms of alcoholism. Other grantees have been able to identify children of alcoholics with a high degree of accuracy from brain wave patterns in response to specific stimuli.

In studies of the relationship of legal drinking age to death and injury on the road, NIAAA grantees have shown that raising the legal age can lead to significant reductions in human casualties and property damage from alcohol-related accidents.

Progress against drug abuse has included development of a new drug for treating heroin addiction, called "naltrexone." This drug blocks the "high" an addict receives from using heroin, thus eliminating its reinforcing effect and improving the user's chance of successful treatment. FDA approval is now pending to make naltrexone available for use at the community level. We believe this is a splendid example of research leading to improved clinical practice.

Finally, among the most important scientific advances of the century are those in the NIMH intramural research laboratories which have led to the ability to visually display brain activity through a Positron Emission Tomography (PET) scanner.

OVERVIEW OF 1984 BUDGET REQUEST

In order to maintain this forward momentum, the President's budget for FY 1984 seeks an increase of 15 percent in the agency's research funding. We believe that this will enable us to respond to the many exciting research opportunities now presenting themselves, and represents a commitment on the part of this Administration to match limited public resources more closely to the huge societal costs of these illnesses. With these funds, we will stabilize our research project grants program at 500 competing investigator-initiated awards, including both basic and clinical research of highest quality. This will include expanding prevention research and our effort to develop and assess new treatment modalities. Additionally, the requested increase will allow us to continue strengthening our intramural research programs.

For mental health research, the budget request is $172.1 million, an increase of $13.8 million from the 1983 level. Nearly one-third of the funds would be used for basic studies of the brain and behavior, including use of the new PET technology to investigate various severe mental illnesses, as well as normal brain processes in cognition, memory, and sleep.

Animal studies of behavioral effects resulting from specific brain tissue grafts also would be continued. Our scientists believe that techniques being used in these investigations have monumental implications for treating mental and neurological disorders.

Depression research would include further study of the specific biological mechanisms through which lithium helps certain types of depressed patients recover. Lithium treatment is estimated to have saved $4 billion in the U.S. over the last decade by restoring many seriously depressed individuals to productivity. Yet it also can

produce severe side effects and is potentially fatal in large doses. Further research into lithium's mechanisms of action is needed to help us devise even safer and more effective treatment.

Prevention research will be a high priority for NIMH in 1984. Four special prevention research centers will be established to foster collaboration among clinicians, researchers, and prevention specialists. Other prevention research will include studies related to suicide prevention and to healthy lifestyles.

With respect to alcoholism research, the President's FY 1984 request is $45.8 million, an increase of $12.5 million. This continues a two-year trend to expand substantially the agency's research on what is clearly among our leading public health problems.

Prevention research also will be a major emphasis for NIAAA, with requested funds for this purpose in 1984 almost double the 1983 level. The Institute will particularly emphasize increased research on preventing alcohol problems among teenagers, including a multi-site cooperative project to develop and test improved alcohol education techniques for this age group.

A priority also would be placed on further investigation of inherited biochemical and physiological factors in susceptibility to alcoholism. Of particular importance are planned studies to identify genetic markers of this susceptibility and to pinpoint the factors contributing to high risk.

Among the most tragic outcomes of alcoholism and alcohol use are its effects on the unborn. In FY 1984, research would focus on the question of reversibility of in utero damage caused by alcohol. NIAAA also would continue to assess the nature and degree to which moderate drinking, and drinking prior to pregnancy, may harbor risk to the fetus.

The intramural alcohol clinical research program, located at NIH, will achieve full operational status by 1984. Along with new studies to be initiated there, the intramural scientists will continue a cooperative project with the Department of Defense to refine a promising procedure developed at NIAAA for diagnosing alcoholism and alcohol-related liver disease.

In responding to nationwide concern about teenage alcohol abuse, the NIAAA has led a key departmental Initiative to combat this problem. The Initiative includes 10 conferences on prevention of teenage alcohol abuse for school administrators and PTA's, a national Secretary's Conference for Youth highlighting programs to fight Drinking and Driving, 14 conferences to assist local communities in the development of treatment programs for teenagers, and dissemination of new prevention publications. This momentum will be continued in 1984 through additional educational activities and further research on treating adolescent alcohol problems.

Turning to drug abuse, the President's FY 1984 request for research is $56,160,000, an increase of $9.1 million over 1983. These funds would complete the relocation of the NIDA Addiction Research Center, the Institute's intramural research facility, to Baltimore, Maryland. As the Subcommittee is aware, re-establishment of a fully operational, integrated intramural research program has been a high priority of the National Institute on Drug Abuse for several years, and in 1984 we will see its achievement.

NIDA's extramural research in FY 1984 would encompass basic and applied studies in all major categories of illicit drugs, giving special attention to marijuana and to cocaine and other stimulants.

NIDA would expand its research on the acute effects of marijuana on cognitive and behavioral performance, including a condition called "amotivational syndrome," characterized by loss of motivation, decreased school performance, and frequently also by alienation from the family. It is also vital to learn more about the impact of chronic use of marijuana on the brain and immune and reproductive systems, and about its potential as a carcinogen.

NIDA also would continue its vital research effort on cigarette smoking as an addiction. The Institute would continue a range of projects aimed at analyzing behavioral characteristics of tobacco users, and at clarifying the role of nicotine in perpetuating cigarette smoking. Also being investigated is an experimental nicotine-containing product for helping people stop smoking.

The President's budget request for research training in all three of our Institutes is approximately equal to the 1983 program level, including $15.5 million for NIMH, $1.0 million for NIDA, and $1.2 million for NIAAA. Training of new researchers is crucial to the long-range success of all of our scientific research endeavors. The proposed budget would support 1,000 trainees in these three fields, providing them a 5 percent increase in stipends.

In addition to supporting and conducting research, the agency also pursues its mandate through national data collection, providing technical assistance, information dissemination, consensus development activities, prevention projects, and a variety of collaborative projects with other agencies and the private sector. In the area of prevention, for instance, the 1984 request includes funds for a number of educational activities to reduce alcohol, drug abuse, and mental health problems. As one example, increases in direct operations are requested for both NIAAA and NIDA to conduct media campaigns to discourage teenage alcohol and drug abuse.

In our research and prevention programs mentioned above, we have been mindful of the valuable Institute of Medicine study and report on "Health and Behavior." In 1984, we will continue to explore every opportunity for collaborative medical and behavioral studies to strengthen our ability to prevent lifestyle risks such as excessive alcohol consumption, drinking and driving, illicit drug use, and cigarette smoking.

The mental health clinical training program is proposed for phaseout in fiscal year 1984, consistent with elimination of funding for alcohol and drug abuse clinical training in 1983. It is the Administration's position that Federal funds to train clinicians is a lesser priority at this time than health research. In part, this is due to the fact that, unlike in the past, ample clinical training opportunities exist without direct Federal support. NIMH will continue to fund clinical research training to prepare researchers who also have clinical skills.

Federal funding for the NIMH Community Support Program also will be discontinued in 1984. This program has funded demonstration projects in 39 States, and will have funded 6 more in 1983. These

have shown that States and communities can work together to provide the required network of resources to care for chronically mentally ill persons in our society.

The President's request for FY 1984 excludes block grant funds from ADAMHA's budget, proposing instead that this program be administered by the Office of the Assistant Secretary for Health. We have received favorable reports on the block grant as a funding mechanism, and the Administration is committed to continuing its support for services through this approach, with no reductions proposed in 1984.

Mr. Chairman, I shall be pleased to answer any questions the Subcommittee may have. Thank you.

Saint Elizabeths Hospital

Mr. Chairman and members of the Committee:

I appreciate this opportunity to discuss the programs of Saint Elizabeths Hospital. Since we last appeared, considerable progress has been made both in the area of patient treatment and in our efforts to make the Hospital financially self-sufficient. Patient care progress is evidenced by:

- o An eleven percent reduction in the rate of rehospitalization for outpatients.
- o An eight percent decrease in admissions of patients screened by the intake unit.
- o A reduction in the average length of stay from 16 days to 11 days.
- o A drop in the inpatient census by approximately six percent since last year.

Considerable progress has also been made in the area of patient care financing. Beginning this year, SEH's reimbursement structure has been revised to provide the Hospital authority to bill and collect fees from patients and their public or private insurers. The only collection restriction remaining is a cap contained in the District of Columbia appropriation which limits the city's liability for its residents' care at Saint Elizabeths Hospital. Therefore, a portion of the Federal appropriation for the Hospital is used to subsidize the cost of care for District residents.

Establishment of Corporation

Last year we told the Committee that a proposal was being developed to create a government sponsored corporation to administer District of Columbia public mental health services including Saint Elizabeths Hospital. Since that time, our focus has been on the budget and Saint Elizabeths Hospital, to assure that merger of the budget into the corporation will reflect the appropriate allocation of financial responsibility for delivery of public mental health and substance abuse services between the Federal and District governments. Having achieved this goal, as reflected in the FY 1984 budget, we will propose corporation legislation.

FY 1984 Budget

The projected program budget of $143.5 million would maintain the FY 1983 operating level. The proposed direct

Federal appropriation for District residents' care is $62.7 million. The funding structure reflects our recommendation to reduce the direct Federal subsidy, reasonably increase the District government's share of the costs of its residents' care, and continue last year's policy of generating revenues from all other users.

Last year the District contribution totalled $38.8 million - $24.7 million of the capped payment plus $14.1 million from Federal Financial Participation in Medicaid. In 1984 we are proposing that the capped payment be increased by $29.9 million to $54.6 million. This includes $9.0 million for increased participation in inpatient costs, a $15.4 million increase for care delivered to District residents who do not require acute psychiatric care but require nursing care, $3.3 million for the District share of start-up costs for the proposed corporation, and a payment of $2.2 million for outpatient services delivered to residents of city catchment Area D. When the $14.1 million in Federal funds projected to be paid as Medicaid Federal Financial Participation is added to this amount, the total D.C. contribution for 1984 will be $68.7 million.

It should be noted that the major portion of the total increase, $15.4 million for patients in need of nursing care, is consistent with the District's commitment, under the Dixon Plan, to provide nursing services to those patients at the Hospital who require nursing but not acute psychiatric care. If the District wishes to care for these patients in a setting other than Saint Elizabeths, services would be reduced accordingly and this nursing care payment would be appropriately adjusted. These increases are consistent with our long-term strategy to gradually shift funding responsibility for the delivery to District resident public mental health services to the District government over the next ten years.

In addition to the above, $12.1 million of the Hospital's budget will be collected as reimbursement from Medicare, private insurance, individual payments, and payment by other Federal and State agencies. Payments from others will be full reimbursement for care delivered, including Virgin Islands' residents. Approximately $3.6 million will be paid by NIMH for support of a portion of its intramural research program which is located at the Hospital.

Other Activities

- The Hospital continues to maintain its two-year Joint Commission on Accreditation of Hospitals accreditation and its Medicare certification, and it continues to fulfill its obligations under the Dixon Final Implementation Plan.
- On December 27, 1982, SEH was awarded Medicaid certification by the District retroactive to October 1, 1982.
- In October 1982, the Federal District Court ordered a moratorium on all transfers of outpatients from the Hospital to the District as provided in the Dixon Plan. The court held evidentiary hearings in December on the plaintiffs' motion to hold the District in contempt and for appointment of a special master to oversee the District of Columbia's implementation of the Dixon Plan. This decision is now under advisement. No similar action was taken against the Hospital. While awaiting the court

to rule, SEH continues to provide services to all outpatients on its rolls without budgeted funding.

- o During the past year several renovation contracts were awarded to improve the Hospital's physical plant including:
  - Eight patient care buildings and a central kitchen,
  - Upgrading of utility systems, and
  - Four patient support buildings.
- o During FY 1984 we plan to continue the review of commercial/industrial type Hospital operations to determine which, if any, can be performed at less cost through a contract with private industry.

Mr. Chairman, I will be pleased to answer any questions which you or members of the Committee may have.

Biography of William E. Mayer

William E. Mayer, M.D.
Administrator
Alcohol, Drug Abuse, and Mental Health Administration
(Includes National Institute on Alcohol Abuse and Alcoholism; National Institute on Drug Abuse; and the National Institute of Mental Health)
5600 Fishers Lane
Rockville, Maryland 20857

FORMER POSITIONS:

1980 - 1981	Medical Director, San Diego County Department of Health Services, San Diego, California
1977 - 1980	Chief, U.S. Army Europe Alcoholism Treatment Facility, Stuttgart, Germany
1975 - 1977	Associate Clinical Professor of Psychiatry, University of California, Irvine, College of Medicine and Associate Chief of Staff, Veterans Administration Hospital, Long Beach, California
1973 - 1975	Chief Deputy Director of Health and Director, California State Department of Health
1971 - 1973	Chief Deputy Director of Mental Hygiene and Director, California State Department of Mental Hygiene
1965 - 1971	Director, Community (County) Mental Health Programs in Contra Costa, Humboldt, and Del Norte Counties, California

U. S. Navy - 1946-1952:

Chief of Psychiatry, U. S. Naval Hospital, Yokosuka, Japan - 1950.
Chief of Psychiatry, U. S. Hospital Ship Repose - 1951.
Medical Battalion Executive Officer and Commanding Officer, E Medical Company, First Marine Division Korea - 1951-52.

U. S. Army 1952, 1960-1965:

Psychiatrist, Special Medical Intelligence Study of Korean POW's.
Instructor, Medical Field Service School, Fort Sam Houston.
Chief of Psychiatry, U. S. Army Hospital La Chapelle, and Psychiatry Consultant, Communications Zone Europe 1957-58.
Regular Course, USA Command and General Staff College, Fort Leavenworth - 1960-61.
Instructor, Medical Field Service School - 1961-62.
Division Surgeon, 11th Air Assault Divison - 1962.
Chief of Professional Services, Office of the Surgeon, U. S. Continental Army Command.

EDUCATION:

Undergraduate - University of Washington, 1940-1942
Northwestern University, 1942-1943 (B.S.)

Graduate - Northwestern University Medical School, Chicago, B.M. - 1946, M.D. - 1947.

Internship - U.S. Naval Hospital, Philadelphia

Residencies - (1) U. S. Public Health Service Hospital, Forth Worth
(2) Langley Porter Neuropsychiatric Institute, University of California Medical Center, San Francisco

Military - (1) Medical Officers Advanced Course, Medical Field Service School, Brooke Army Medical Center, Fort Sam Houston
(2) Regular Course, U.S. Army Command and General Staff College, Fort Leavenworth, Kansas
(3) Aerospace Medicine, Brooks Air Force Base and Fort Rucker, Alabama
(4) Nuclear Weapons Employment Officer Course, U.S.A. Command and General Staff College, Fort Leavenworth, Kansas
(5) Chemical and Bacteriological Warfare Course, Dugway, Utah

HONORS AND AWARDS:

Alpha Omega Alpha, National Medical Honor Society
Freedoms Foundation at Valley Forge, National Award
National Management Association, Gold Medal-Leadership
Resolution of Commendation: Georgia Legislature
Resolution of Commendation: Texas Legislature
Bronze Star, Combat V, U.S. Marine Corps
Bronze Star, U.S. Army
Navy Unit Citation
Marine Corps Unit Citation
Army Commendation Medal

PUBLICATIONS IN:

Yale Scientific Review
"Soviet Total War" - U.S. Senate Publication
U.S. News and World Report on POW's in Korea
Baylor University Press
Kentucky State Teachers Association Journal
Symposium on Management of Mass Casualities, Medical Field Service School, Fort Sam Houston

TEACHING POSITIONS:

Northwestern University Medical School. Instructor in Anatomy.
University of Texas/San Antonio. Instructor in Psychology and Public Health.
University of California Medical School/San Francisco. Instructor in Psychiatry.
Contra Costa College. Instructor in Psychology.
College of the Redwoods. Instructor in Psychology.
University of California/Irvine, College of Medicine. Associate Clinical Professor of Psychiatry and Academic Administrator.
Instructor, Field Medical Service, Medical Field Service School, Brooke Army Medical Center.

GUEST LECTURESHIPS:

U. S. Military Academy, West Point
U. S. Naval Pre-flight School, Pensacola
U. S. Army Intelligence Center, Fort Holabird, Maryland
Georgetown University
Louisiana State University
University of Florida
University of Arizona
University of Alabama
University of Washington
Baylor University
Livermore Radiation Laboratory, Berkeley
Temple University
Catholic University
George Washington University
Harvard University
Walter Reed Army Medical Center

PERSONAL:

Born: Chicago, Illinois, 24 September 1923
Married, 4 Children

INTRODUCTION OF ASSOCIATES

Dr. MAYER. Thank you, Senator.

Mr. Chairman, I am pleased to present to you this morning Dr. Herbert Pardes, Director of the National Institute of Mental Health;

Dr. William Pollin, the Director of the National Institute on Drug Abuse;

And behind me is Mr. Loren Archer, the Deputy Director, who has been Acting Director, of the National Institute on Alcohol Abuse and Alcoholism;

And we are accompanied by Mr. Anthony Itteilag from the Department headquarters.

OPENING REMARKS

As you very kindly offered, I do have a short opening statement. A longer one has been prepared for the record.

I would like to point out that alcohol, drug, and mental health problems are among the Nation's most serious, costing us at least $1.6 billion a year.

Of course, in addition and more important than that is the human side of these disorders, particularly the massive number of people, over 25,000 a year including 10,000 youngsters, killed on the highways in drunk driving accidents or accidents related to alcohol.

We still have the highest level of drug use among our young people of any Western industrialized nation. We know about one out of every five Americans at some time in his life has a serious depression, and that there are more than 1 million schizophrenics in this country.

So our budget proposes to address these problems primarily by advancing what has become an explosive growth in alcohol, drug abuse, and mental health research opportunities; by helping to devise improved treatment and prevention methods; by disseminating the burgeoning knowledge in this field both to the public and to the people who are offering treatment.

We have never had a better year for expanding our research, because never before has there been the quality and the extent of public interest that there has been in this past year. Interest on the part of the Congress is no longer confined to one or two people who had a special kind of parochial interest in these fields, but it has become very widespread.

We have developed new technologies that were hardly dreamed of a few years ago and as a result, the research opportunities are greater than they have ever been.

Some of our breakthroughs I am sure you have heard about. One, while very preliminary, suggests that a drug that we have been using for the treatment of narcotic overdoses actually has application in reducing the memory deficit connected with senility or Alzheimer's disease.

We have discovered also at least two separate inherited forms of alcoholism, one dependent on the environment, the other totally independent of it.

We have discovered data about reward circuits in the brain which can be shortcircuited resulting apparently in a greater predisposition to become addicted to various kinds of drugs, but particularly opium derivatives.

We are asking for about a 15-percent research budget increase this year, and we feel that this is moving toward matching public resources with the burden that these illnesses produce.

We also intend, through this budget request, to provide stability to our research grant funding which has fluctuated somewhat in the last few years. We are going to continue with basic research, with genetic research, with prevention research, with special programs on the aging and on children. And we are going to upgrade our intramural research programs as part of a process that has been going on for several years.

Finally, we are developing ways to influence the lifestyles of people so as to reduce excessive alcohol consumption, drinking and driving in combination, avoiding illicit drug use, cigarette smoking, the other kinds of things that impact not just on this field of health, but on many others, especially cancer, heart disease, and stroke.

Our budget request that is before you does not include the funds for the block grant which are included in the Department budget.

Senator RUDMAN. Does that conclude your remarks?

Dr. MAYER. Yes; it does.

Senator RUDMAN. Thank you very much, Dr. Mayer.

I understand my colleague has to leave for another hearing early so I am going to yield to him for whatever questions he may have.

EXTENT OF DRUG ABUSE AND MENTAL HEALTH PROBLEMS

Senator PROXMIRE. Thank you very much, Mr. Chairman. I appreciate that. I have to be at the Agriculture Committee at 9 o'clock.

Dr. Mayer, I didn't hear all you just said, but I think I he[illegible] much of it. And I am tremendously impressed and depressed.

The fact that drug abuse is more prevalent in this country than any other developed country in the world is appalling.

I notice that you estimate that drug abuse and mental health problems cost $106 billion refers back to the year 1977. That is a long time ago. Can't we bring those figures up to date, make them more current? Are we making progress or not?

Dr. MAYER. It is a long time ago, and I am getting a little uneasy about using 1977 figures. But a valid assessment is a costly and complex undertaking which requires a major investment on our part. So we are still using those figures, but recognizing that inflation alone would cause them to rise.

Surely, the question needs to be asked whether the Federal investment in these fields has had a significant impact in cutting down the cost to the Nation, and we don't know that for sure at this point.

Believe me, it has at least slowed the increasing cost that would otherwise have taken place.

To illustrate we have found that the application of one drug alone, lithium, in the treatment of manic depressive disorders has, over the past 10 years, probably saved about $10 billion in costs connected with people having that disease.

Senator PROXMIRE. You indicate that drug abuse is more prevalent and serious here. How does our problem compare to that of other countries? Is our problem twice as bad, three times as bad, or just a little worse than that of other countries?

Dr. MAYER. If I may, I would like to ask Dr. Pollin, Director of the National Institute on Drug Abuse to answer that. I think he can do so more precisely.

Senator PROXMIRE. Yes, sir.

Dr. POLLIN. Senator Proxmire, we are in the enviable position of having a much better data system than any other developed country.

Senator PROXMIRE. How accurate are the data produced by other countries?

Dr. POLLIN. Other countries rely for the most part on informed estimates. Some of our grantees who have been responsible for providing us with hard data have recently been providing epidemiologic assistance to the European community, and other parts of the world. They have gotten to know the situation in other countries. And it is on the basis of their estimates and World Health Organization estimates that we make that statement.

ALCOHOLISM

Senator PROXMIRE. Do the drug abuse figures include alcoholism?

Dr. POLLIN. The figures which we cited on a comparative basis do not include alcohol.

Senator PROXMIRE. What effect would that have on the comparison? Would we still be No. 1 if the data included alcohol? I understand that is a very serious problem in a country like Russia.

Dr. POLLIN. Yes; it is a major problem there.

In terms of per capita consumption of alcohol, we fall in a mid-range level, compared to other nations.

Senator PROXMIRE. Why wouldn't the data include alcoholism? Certainly, that is an abused drug. I understand it is the most widely abused drug we have.

Dr. POLLIN. I would think nicotine was the most widely abused drug that we have, but apart from that, we don't include them in our estimates because they are two separate data systems.

Senator PROXMIRE. You don't include either nicotine—that is, smoking—or alcohol when you talk about drug abuse, is that right?

Dr. POLLIN. When we compared the level of drug abuse in this country, to the rest of the world, we are not including licit drugs.

Senator PROXMIRE. You cite a $106 billion figure. That estimate does not include nicotine or alcohol abuse, is that right?

Dr. POLLIN. No. The $106 billion doesn't include——

DRUG ABUSE

Senator PROXMIRE. Along this line I would like to explore one other point. There is a general impression, I think, that a few of the biggest cities are drug centers—New York, Miami, and some of the other very, very large cities. Is it generally true that the biggest part of the abuse problem is confined to the big cities or is it a problem in the general population?

Dr. POLLIN. One cannot generalize with respect to all drugs. With respect to narcotics, it is true that a number of the largest cities have by far the predominant extent of the problem.

With regard to other drugs, there has been a dramatic homogenization, if you will, of drug use across the country.

Senator PROXMIRE. Is there any ethnic or racial distinction—Hispanic, black, white?

Dr. POLLIN. The overall tendency has been for those distinctions to disappear. A few drugs are exceptions. Inhalants, for example, are much more prevalent among Hispanics and American Indians.

Senator PROXMIRE. Can you tell us why the drug problem among American youth is worse than among the youth of other nations?

Dr. POLLIN. We don't know for certain. It is a very complex issue. We think we have a better understanding of why there has recently been a significant improvement in terms of drug use among American youth.

We have specific pictures of attitudinal changes—greater awareness of health risk. The original tremendous increase in drug use by American youth is a very complex issue and would take, I think, too much time at this hearing.

Senator RUDMAN. I am a little confused. I understood you to indicate we had made some improvements.

Dr. POLLIN. Very much so.

EXTENT OF ALCOHOL PROBLEMS

Senator PROXMIRE. On the other hand, you say there is an increase in the use of drugs. Can you give the figures comparing, in the first place, adult problem drinkers or alcoholics 10 years ago and today?

Dr. POLLIN. Overall levels for alcohol consumption have tended to remain essentially flat or show a very gradual increase.

Senator PROXMIRE. Consumption and abuse are different.

Dr. POLLIN. Yes.

Senator PROXMIRE. You might have a steady consumption, but your level of abuse might be improved.

Dr. POLLIN. I don't believe there has been any data suggesting that the ratio of drinkers to all those who present with problems in the field of alcohol has changed, but Dr. Mayer is, I think, much more knowledgeable about that.

Dr. MAYER. We continue to estimate there are about 10 million alcoholics in this country needing treatment. And our surveys of high school seniors show that about 3 million young people by their own description state that they are having active problems with alcohol use. How that compares precisely with——

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Senator PROXMIRE. What percentage of young people have a drinking problem?

Dr. MAYER. About 3 million young people.

Senator PROXMIRE. How big a population are we talking about?

Dr. MAYER. I can provide that latter figure for comparison for the record and would be happy to do so.

But the point I wanted to make was our epidemiological abilities and studies in both drug abuse and alcoholism are in the process of becoming very solid. They weren't 10 years ago, so comparisons cannot be precise.

[The information follows:]

TEENAGE ALCOHOLISM

In 1981, there were an estimated 28 million 14 to 20 year olds; 16 million 14 to 17 year olds and around 10 million of these teenagers are 10th to 12th graders. A national survey of 10th to 12th graders conducted by the NIAAA indicated that 29 percent of these students have drinking problems, or approximately 3 million of the 10 million teenagers in 10th to 12th grades.

REDUCING DRUG AND ALCOHOL ABUSE

Senator PROXMIRE. Do you have any comparisons at all? You say one-third of all Americans over 12 are using an illicit substance or a prescription drug for nonmedical purposes. Can you tell us how that compares with, perhaps, 5 years ago?

Dr. MAYER. I don't believe so because we weren't asking those questions 5 years ago.

Senator PROXMIRE. Do you have any targets to shoot at in reducing drug and alcohol abuse?

Dr. MAYER. Specific, viable goals?

Senator PROXMIRE. Yes, sir.

Dr. MAYER. We have not at this point set a 10-percent reduction, 15-percent reduction, that kind of a goal. We believe partly that our ability to do so is going to rest upon one of the things that is in this year's budget which is a substantial increase in our ability to get a good baseline of firm data.

And judging by our suggestion so far in capturing the interest, particularly of young people, where I think real preventive efforts are going to prove most effective, I believe that we can begin setting goals within the next few years of actual percentagewise reduction. One would hope so.

POTENTIAL SAVINGS FROM ADDITIONAL APPROPRIATIONS

Senator PROXMIRE. I have one other question. I am sure you are very sensitive to the difficulty of coming up with statistics which are precise, accurate, and reliable, particularly when you talk about money. It is sad that we have to reduce this problem to money because, of course, each individual case is heartbreaking to the individual, but this is an appropriation committee. We have to look at costs and benefits in selling the program.

Can you give us any notion of how additional appropriations could specifically effect savings, not only as far as the general economy is concerned, but direct savings for the Government so we can have the strongest possible arguments for supporting the appropriations?

Dr. MAYER. I think so. We can already show in our interactions with private industry and their development of employee assistance programs that we are beginning to intercept early cases of alcohol problems. We encounter other kinds of chemical problems and a lot of emotional problems as well.

Experience with industry has shown that this is a highly cost effective kind of activity and one, in fact, that has not required very much Federal investment because businesses themselves have found out that it is so valuable and they are pursuing it.

We are carrying that further, and we intend to. We can foster further such intervention in other workplaces, in schools, for example, and in Government. We have such programs in most areas of the Federal Government now.

Senator PROXMIRE. My question related to whether or not you are going to be able to show that for a particular additional appropriation you save twice as much money as you spend, or 10 times as much, or some other figure.

Dr. MAYER. I would like to be able to make a simple clear statement like that, but to be totally honest about it we can't say that at this point. We are, after all, in a research mode primarily which involves gaining the knowledge on which to make such comparisons.

We do have some institute studies, for example, that show fairly clearly that when alcoholism treatment is offered through insurance that the ultilization by medically insured people of other medical services drops very significantly. Expecially with regard to the members of an alcoholic's family who utilize other medical services much less—by a factor of about eight times.

One good study in California of civil service employees of the State government demonstrated this. That is the kind of data, I think, that you are asking for.

Senator PROXMIRE. That's very good.

Dr. PARDES. That particular feature is applicable to the mental health field as well, Senator. It has been shown when you incorporate an appropriate mental health service in an appropriate setting, you reduce all other health services.

Senator PROXMIRE. Thank you, Mr. Chairman.

EFFECT OF RECESSION ON HEALTH

Senator RUDMAN. Dr. Mayer, I have a number of questions here, and we will try to conclude in a relatively short period of time if we can.

The recession that we hopefully are just coming out of, there are great concerns as to what this does to people's health. They are under great stress, those that are unemployed, the families. Have you seen an increase in conditions requiring treatment because of this recession that you could correct, doctor?

Dr. MAYER. We expect there is some increase, but no, sir, we don't have firm data that actually proves that it is a direct result of this one additional stress or combination of stresses from economic hardship.

Senator RUDMAN. I was thinking particularly in the area of alcohol abuse. It appears to be at least a situation currently in evidence in areas of high unemployement, particularly alcohol abuse, beyond normal.

Dr. MAYER. Yes; and we think that is true. It isn't necessarily true that those people come to our attention or come for help.

JOBS BILL SUPPLEMENTAL

Senator RUDMAN. In the supplemental, we provide additional funds for alcoholism, mental health, and drug abuse. Can you tell us whether funds have been obligated to the States?

Dr. MAYER. In the supplemental?

Senator RUDMAN. Emergency aid, the jobs bill, Dr. Mayer.

Dr. MAYER. The $30 million that was put in for addition to the block grant?

Senator RUDMAN. Right.

Dr. MAYER. This has been allocated to the States, yes, sir. And we allocated it according to the same formula that allocated the initial block grant distribution. However, awards have not yet been made.

POLICY OF 500 NEW AND COMPETING RESEARCH GRANTS

Senator RUDMAN. Now, we have just been through a thorough examination of the NIH request where the initial decision to support 3,600 grants was overruled in favor of 5,000 grants which is congressional policy.

Now, they may have to absorb the cost of decision by cutting other areas. This is raised by way of background because your request includes substantial increases in research in all areas—ranging from 8.7 percent for mental health to 19.5 percent for drug abuse totaling $32.5 million additional dollars.

The justification on page 21 indicates your goal to support 500 new and competing grants. In order to sustain this level of research in the future, it is going to require a very substantial commitment of future resources.

Is it the administration policy to provide an annual level of 500 new and competing grants plus necessary funds for continuations or is this going to be a one-time change?

Dr. MAYER. It is the administration's intention to stabilize our research at not less than 500 grants per year. And that reflects the fact that for about 10 years up until 1981, our average number of grants was a little over 500 new and competing grants every year.

We did look very carefully at our research portfolio to make sure we were no longer funding some of the more general kinds of studies that didn't have direct relevance to the problems connected with alcohol, drugs, and mental health. That dropped us somewhat for a couple of years.

But we have advocated for a number of years that our level should return to not less than 500 a year. And that is what we are proposing.

Senator RUDMAN. Could you or possibly Mr. Itteilag tell us what kind of health built-in increase we are talking about in the future years, the out-years impact of this decision?

Dr. MAYER. You mean as a result of having 500 this year?

Senator RUDMAN. Yes.

Dr. MAYER. It doesn't make for a substantial or significant increase in the outlays, probably about 10 percent a year.

Senator RUDMAN. You might check that for the record.

Mr. ITTEILAG. I think that's correct, Senator. Once we have reached the 500 level, the number of continuing commitments levels off as well after a couple of years. And one would expect, therefore, when we reach that point that the dollars would vary only by an inflation factor.

[The information follows:]

EFFECT OF STABILIZATION AT 500 NEW/COMPETING AWARDS

If the number of new and competing research project grants were stabilized at 500 in 1984, the impact on out-year funding for the total project grant activity would be as follows:

	Increase in project grant funding (Percent)
1985	+23.1
1986	+15.5
1987	+5.7
1988	+3.7
1989	+4.7

It should be pointed out that project grants comprise only 53 percent of our total research program. The 1985 increase in project grants costs would thus only increase our total research budget by about 12 percent.

INTRAMURAL RESEARCH

Senator RUDMAN. Did the bulk of your research funds go to extramural as opposed to intramural research?

Dr. MAYER. That is correct.

Senator RUDMAN. Even this varies. For instance, in the mental health and alcoholism areas, 30 percent of the 1984 funds will go into your intramural program. In drug abuse, about 10 percent is in the intramural program.

Can you explain to the committee how you determine distribution between in-house efforts and extramural projects?

Dr. MAYER. Well, our principal emphasis has been and will continue to be the extramural program. There have been fluctuations in the intramural which are not necessarily a result of our making a conscious decision at the outset on a certain 20 percent.

In drug abuse, for example, we have been in the process of moving the entire intramural laboratory from Lexington, Ky., up to Baltimore. That was done because we could no longer use Federal prisoners as subjects. So the clinical part of that research program has been moved

to Baltimore. And the beginnings of refurbishing of the Baltimore City Hospital to accommodate that has caused considerable demand for funds. In the 1984 budget, we are continuing that. But once the program is established, their intramural expenditures will level off.

Similarly in mental health. We provided for the purchase of a magnificent piece of psychological equipment called the PET scanner, a positron emission tomography device, which can show us actual brain function while it is happening. That required a one-time major investment.

In alcohol, we are in the process, in the final stages now, of opening a clinical laboratory of 10 beds, including associated preclinical labs, in the Clinical Center at NIH campus. And that has resulted in increases in the amount of money necessary for that program.

These are all good examples of why the funding fluctuates.

SCHIZOPHRENIA

Senator RUDMAN. Dr. Mayer, schizophrenic disorders are costing an enormous amount of money each year. Given the facts of the enormous commitment that must be made to this kind of disorder in terms of the hospitals, what are you doing in terms of research? How much have you devoted to research in the area of schizophrenia?

Dr. MAYER. Some very special programs are being conducted.

I would like to ask Dr. Pardes of the National Institute of Mental Health to reply to this.

Dr. PARDES. Our total budget for schizophrenia research jumped to $23 million in 1984. We agree this is one of the most serious and chronically disabling disorders that the health field faces.

We have just recently called in the number of experts from around the country to discuss appropriate research directions in schizophrenia, about attracting new researchers to the area and developing new leads.

We now know that schizophrenia is a term which encompasses a number of diseases. Rather than investigating it broadly, we are trying to identify the subcategories and thereby look for particular causes related to those subcategories. This was the basic strategy used in mental retardation which resulted in the discovery of some of the causes of some of the various types of retardation.

There have been some notable advances in treatment but we think schizophrenia is one, certainly, of the major diseases into which we have to put major investment in order to get answers about its etiology.

INDIRECT COSTS

Senator RUDMAN. I will go on now to a few questions on indirect research.

A recurring issue has been the administration's attempt to control the indirect costs of research performed by grantees. Last year, a 10-percent reduction was proposed and rejected. This year, your budget simply states that $4 million will be saved by reducing administrative overhead costs.

As I understand, you will redefine allowable indirect charges. Am I correct in that understanding?

Dr. MAYER. Essentially, that's true, Senator. Our posture vis-a-vis the indirect charges is consistent with that of the National Institutes of Health.

The indirect costs are, of course, valid costs which are individually negotiated with each research grant. It is going to take a careful review and an acute look at what we can allow in order to reduce these costs by $3.9 million.

Senator RUDMAN. Is this something you are working on with the various universities and other grantees, consulting with them, to try to have some sort of a determination as to what is agreed on as proper indirect costs and those that are not?

Dr. MAYER. Yes; Dr. Brandt, Assistant Secretary for Health, has called a meeting that I attended involving representatives of major universities from all around the country to discuss this issue.

Senator RUDMAN. I think it might be useful if you would supply for the record some background on the character of these meetings, who was involved, et cetera. We would like to have that information, Mr. Itteilag.

Mr. ITTEILAG. Yes, sir, we would be happy to provide it.

[The information follows:]

MEETING ON INDIRECT COSTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH

In early 1983 the Assistant Secretary for Health initiated plans for a discussion on indirect costs of biomedical and behavioral research. The Public Health Service, in particular, NIH, compiled a listing of universities and research organizations which might want to participate in such a discussion. This list was sent to three representatives of the university and scientific research community for review and suggestions. Then, a final list was prepared; the meeting was scheduled for February 17, 1983, and invitations were sent to these university and research officials. (A listing of the attendees at this meeting is attached.)

The meeting was conducted according to the following agenda:

1. Statement of the problem—PHS perspective presented by Drs. Brandt and Wyngaarden.
2. Statement of the problem—Scientific community perspective presented by invitees.
3. Summary of PHS policies options: a. short-term, b. long-term. Presented by Dr. Raub, NIH.
4. Commentary on PHS policy and options, presented by the invitees.
5. Concluding remarks, presented by Drs. Brandt and Wyngaarden.

Although this meeting provided a forum for the exchange of ideas and positions for both the administration and the scientific community, there was no resolution on the problem of indirect costs.

UNIVERSITY/RESEARCH SOCIETY OFFICIALS

Dr. John R. Hogness, president, Association of Academic Health Centers.
Dr. John F. Sherman, vice president, Association of American Medical Colleges.
Dr. Lattie Coor, president, University of Vermont.
Ms. Carol R. Scheman, director of Federal relations for health and biomedical research, Association of American Universities.
Dr. William Danforth, chancellor, Washington University.
Milton Goldberg, executive director, Council on Government Relations.

Dr. John DiBiaggio, president, University of Connecticut.
Dr. Frederico Welsch, president elect, Association of Independent Research Institutes, and budget analyst, Delegation for Basic Biomedical Research.
Dr. Mary Jane Osborn, president, Federation of American Societies for Experimental Biology.
Dr. Robert Clodius, president, National Association of State University and Land-Grant Colleges.
Dr. John A. D. Cooper, president, Association of American Medical Colleges.
Joseph Warner, director, contracts and grants, Yale University.
Dr. C. D. Cox, chairman, committee on medical microbiology and immunology, Public and Scientific Affairs Board, American Society for Microbiology.
Dr. Linda Wilson, associate vice chancellor, University of Illinois at Urbana.
Dr. Robert Sproull, president and chief executive officer, University of Rochester.
Jerold Roschwalb, director of higher education and governmental relations, National Association of State Universities and Land-Grant Colleges.

PHS OFFICIALS

Dr. Edward N. Brandt, Jr., Assistant Secretary for Health.
Dr. James F. Dickson, III, Senior Advisor for Environmental Affairs, Office of Assistant Secretary for Health.
Wilford J. Forbush, Deputy Assistant Secretary for Health Operations, Office of Assistant Secretary for Health.
Dr. William E. Mayer, Administrator, Alcohol, Drug Abuse, and Mental Health Administration.
Dr. James B. Wyngaarden, Director, National Institutes of Health.
Dr. Thomas E. Malone, Deputy Director, National Institutes of Health.
Dr. William F. Raub, Deputy Director, Extramural Research and Training, National Institutes of Health.
Norman D. Mansfield, Director, Division of Financial Management, National Institutes of Health.
Robert L. Trachtenberg, Deputy Administrator, Alcohol, Drug Abuse, and Mental Health Administration.

PROVISIONS OF CIRCULAR A-21

Mr. ITTEILAG. I would point out for the record that we were asked by the House and Senate to prepare a report on this matter. And that report, while it wasn't forthcoming as quickly as we would have liked, was provided to the committee as of last Friday and discussed the issue in some detail.

Senator RUDMAN. Of course, we have the other problem as to what extent you might act independently on this because there is an OMB circular which governs this Government-wide. Do you take exception to that circular?

Mr. ITTEILAG. In the short run, Senator, we would be pursuing a policy somewhat different than other Federal agencies. But in the long term, it is clear that something needs to be done to restrain these costs, and if something is to be done, it should be done on a Government-wide basis.

It would involve a reconsideration of certain provisions of circular A-21. And, therefore, it would affect others in the Federal Government who fund research such as Defense Department, National Science Foundation, et cetera.

Senator RUDMAN. Obviously, the interest in this line of questioning is

the $4 million that you are assuming as savings is based on a policy which has yet to be evolved, a policy which could be in conflict with other—it might be a good policy, but it might be in conflict with other policies of the Government.

So we would like more information on that.

Dr. MAYER. Happy to supply it.

[The information follows:]

INDIRECT COSTS

The Department has submitted to the Congress a report on the indirect costs of medical and behavioral research. The report contains four short-term options which would apply only to the research grant activities of ADAMHA and NIH. As a result, other Federal agencies would be, during this interim period, utilizing different policies. The report also contains two long-term options. Each of these contemplates Federal-wide applicability and would mitigate the types of policy conflicts to which you refer.

REPORT ON THE INDIRECT COSTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH

INTRODUCTION

In its report on the fiscal year 1983 budget for the Department of Health and Human Services, the House Committee on Appropriations stated:

> The Committee is persuaded that indirect costs are a legitimate component of the costs incurred in performing biomedical research and should be adequately reimbursed. The Committee is also concerned by the widespread perception that Federally sponsored research may be bearing more than its fair share of these costs. The indirect cost level as a percentage of the total costs of research grants has increased from 15% in 1966 to 20.5% in 1972, and 29.5% in 1981. In 1980 and 1981 reimbursements for indirect costs grew faster than the general inflation rate, whereas direct costs of doing research did not. The Committee requests the Secretary of Health and Human Services, in cooperation with the NIH Director, to make a careful review of this matter, including consultation with the universities and other research organizations most directly affected, and to submit a report setting forth conclusions and appropriate recommendations to the Committee for discussion in advance of hearings on the 1984 budget request. The Committee also intends to ask the Comptroller General to make another independent review of the subject.

The following report has been prepared by the National Institutes of Health (NIH) of the Department of Health and Human Services (DHHS), in response to this request.

STATEMENT OF THE PROBLEM

Expenditures for the indirect costs of biomedical and behavioral research have been growing at a faster rate than direct costs in recent years. Since 1966, when the then Department of Health, Education, and Welfare, now the Department of Health and Human Services, made full reimbursement of indirect costs a central element of its grants policy, indirect costs have been consuming an ever-greater fraction of the funds available for grants, accounting for 30% of the total in FY 1982. As illustrated by the table (Attachment I) showing recent trends in the average amounts awarded for NIH individual investigator initiated research project grants (RO1s) in terms of constant FY 1970 dollars, the support of direct costs remained essentially level from FY 1970 through FY 1982, in spite of the increasing complexity of research. Indirect costs during that same 13 year period rose more than 50%. The inevitable consequence of this trend has been that proportionately fewer dollars have been available each year to meet the direct costs of research.

Indirect costs are fully reimbursed in strict accordance with a negotiated rate based upon the allowability and research relevance of particular expenditures. However, these expenditures are not subject to further evaluation such as that which peer reviewers and agency staff invariably apply to proposed direct cost expenditures. Indirect costs thus have had preferred access to grant support dollars.

The DHHS believes that its expenditures for indirect costs should be made subject to new restraints. In these times when the needs and opportunities to gain new knowledge in the life sciences far outstrip the funds which society realistically can provide, it seems more important than ever to support as many investigators as possible. It is also important to avoid the erosion in public confidence that could occur if all budget categories do not share in the adaptation to economic restraint.

BACKGROUND

The indirect costs of research are those expenses that cannot readily be traced to specific projects. Usually included under this classification

are expenditures for such items as utilities, depreciation, maintenance, departmental, general and research administration, and libraries.

The categories of costs that are usually classified as indirect and the criteria for apportioning those costs are prescribed in OMB Circular A-21. Indirect costs are apportioned between research and the other major functions of a university (e.g., teaching), based on various cost allocation procedures, and the portion ultimately identified with research is then further distributed to individual research projects by an indirect cost rate. The rate is expressed as a percentage of the direct costs (or direct salaries and wages) of an institution's research. The indirect costs chargeable to each research project are determined by multiplying the direct costs of that project by the indirect cost rate approved by the Government. Although not required by OMB Circular A-21, with few exceptions, the DHHS policy provides for the payment of full indirect costs. Indirect costs are not measures of comparative efficiency, however, because institutional management structures and accounting systems are rarely identical. That is, one cannot assume that one institution is more efficient than another just because it has a lower indirect cost rate.

Indirect cost rates are generally negotiated annually with each grantee institution. The Department of Health and Human Services is the approving Federal agency for about 95% of the colleges and universities performing Federal research. Prior to approving a rate, Federal negotiators assess the institution's indirect cost proposal to determine whether the costs proposed are allowable and relevant to the performance of research and whether the institition's proposed apportionment methods result in an equitable allocation of costs to Federal programs. The negotiators, however, are at a disadvantage in their assessment because Circular A-21 allows certain costs that, under current university accounting practices, are difficult to measure or evaluate for research relevance. This is particularly true for "departmental administration" expenses, which on the average account for in excess of one-third of the indirect cost rate.

POLICY OPTIONS

One change recommended for serious consideration, in conjunction with whichever containment approach (or approaches) may be adopted, is to rescind the current practice of allowing subsequent adjustments, usually upward, to the negotiated rate. The revised practice would be similar to the practice of the National Science Foundation, the Department of Defense, and virtually all other Federal agencies.

In addition, there are several different ways in which expenditures for indirect costs could be limited in FY 1984. Some of these are no more than temporary expedients. Others are potential first steps toward a new model suitable for the long term. These options are discussed individually below.

Short-term Options:

1. Across-the-Board Reduction

   This option, in the form of a 10% reduction, was proposed as part of the FY 1983 budget request. There are two significant advantages to this approach: it would be simple to implement, and it would spread the burden proportionately across the grantee community. A disadvantage of this option is that those institutions that have kept costs down would be penalized along with those that have not. If adopted as long-term policy, another disadvantage of this option is that it would encourage efforts to increase indirect cost charges to Federally sponsored projects; i.e., grantees would have an incentive to make their indirect cost rates as high as possible in order to ameliorate the effect of receiving only 90% of the reimbursement for which they qualify.

2. Capping Selective Indirect Cost Components

   This option could be implemented by selectively limiting reimbursement for those components of indirect costs that seem least related to

research, e.g., "departmental administration." The advantages of this option are its simplicity and its focus on constraining the reimbursements that are the most difficult to evaluate and measure relative to research. The disadvantage of this option is a possible shifting of affected costs to direct or other indirect cost components, resulting in a loss of potential savings. In addition, some believe that certain universities would be affected more than others by this policy, due largely to different management structures and accounting systems.

3. Establishment of a Standard Fixed Allowance

This approach is both conceptually and operationally simple, and it could be implemented immediately. If coupled with deregulation in the form of a significant reduction in recordkeeping requirements for grantees (e.g., reduction of time-and-effort accounting and elimination of cost-sharing documentation), a fixed allowance for indirect costs government-wide could be an attractive long-term policy as well. It also would reduce the administrative burdens of the awarding agencies and the Federal staff time required to negotiate rates. The principal disadvantage of a standard fixed allowance is that it almost necessarily would be arbitrary and would not affect all grantees equitably. Another disadvantage of this option if continued beyond FY 1984, is that it could result in attempts to circumvent the standard fixed allowance by shifting costs from the indirect cost category to the direct cost category to an extent greater than might otherwise be either practical or appropriate. Consequently, if this approach were used, it would be necessary for the government to define direct costs more precisely.

4. Establishment of a Fixed Allowance Tailored to Each Institution's Historical Level

Each grantee could be assigned an individualized allowance for indirect costs by fixing the indirect cost/total cost ratio based on the experience of recent years. For example, the PHS could set indirect cost payments at a level equal to the average percentage of total costs that they accounted for over the last decade. The advantage of this option, in addition to the same deregulation advantages associated with option 3, is that the major impact would be felt by those grantees whose indirect costs have been growing most rapidly in relation to total costs. By contrast, grantees whose indirect costs have been stable or nearly so, as a percentage of total costs, would probably experience little, if any, adverse impact. However, like option 3, the tailored allowance has the disadvantage, if adopted as a long-term solution, of possibly encouraging institutions to shift costs from indirect to direct cost categories in a manner inappropriate either in nature or extent, unless more precise definitions of direct costs were established.

Long-term Options:

All of the short-term options discussed above could be continued indefinitely. Two specific long-term options follow.

1. Redefinition of Reimbursable Indirect Costs

As a long-term solution to the indirect cost problem as well as a means of substantially reducing paperwork, the Department believes that serious consideration should be given to a basic redefinition of reimbursable indirect costs in Circular A-21.

As already pointed out, there are certain types of currently allowable indirect costs which are very difficult to measure or evaluate and are frequently judged to have questionable relevance to research programs.

This is especially true for the indirect cost component referred to as "departmental administration", which consists largely of the salaries and expenses of deans, academic department heads, faculty, etc., related

to administrative activities. There is considerable sentiment that these types of costs are more properly associated with the instruction rather than the research function of universities. This sentiment is reflected in the Circular A-21 formula used to develop indirect cost rates for small colleges which allows 20% of the salaries and expenses of deans and department heads as a standard allowance with no need for further documentation. In the case of the large schools, departmental administration is the largest component of indirect costs (averaging about 35% of the indirect cost rate), and is a major source of paperwork since it requires the use of complex reporting systems to identify the portion of salary costs that may be classified as "administration." Consequently, a more restrictive definition of these costs would not only reduce indirect cost rates, but would also substantially simplify and reduce recordkeeping, remove a major area of disagreement in the audit and negotiation of the rates, and ensure that the rates represent costs which truly benefit research programs. The definitions of other "administration" cost categories, e.g., "general administration," would also need tightening in order to avoid shifting of costs.

This approach would include consideration of more liberal reimbursement for costs associated with the acquisition and operation of university facilities to partially offset the restriction on administrative costs. The costs of acquiring and operating facilities are widely accepted as necessary to the performance of research and are relatively easy to measure and document.

2. Choice of a Fixed Allowance or a Negotiated Rate

This approach would allow the grantee to choose either a fixed allowance or continue the "rate negotiation" process. If choosing negotiation, all cost categories, direct and indirect, would be standardized and there would be an explicit delineation of what types of expenditures could be classified within the categories and claimed as indirect costs. The institutions would also be required to standardize their accounting systems. The major advantage would be the elimination of cost shifting and consistency of application. A major disadvantage would be complexity of implementation; e.g., a more complicated negotiation process initially, significant increased costs associated with making adjustments to institutional accounting systems, cost estimating difficulties prior to implementation, and rigidity in accounting systems. Another serious disadvantage is that the prospects for significant savings are uncertain at best; grantees with indirect costs higher than the standard allowance would probably opt for a negotiated rate, and those with costs below the allowance would opt for the allowance.

RECOMMENDATION

Of the options presented, the DHHS prefers a variation of Short-term Option 4 for FY 1984 or until a more permanent solution is worked out. Before the adoption of this or any other option, we will consult further with representatives of the research community and will apprise the Committee of the results. In implementing the proposed variation of Option 4, each institution's level would be tailored to its own historical experience; those with the lowest levels or growth rates would be undisturbed; and reductions too severe to be absorbed in one year would be phased in. In order to accomplish this, the institution's indirect cost reimbursement would be based on a level equal to its average percentage of total costs over the last decade, but no institution would be reduced below 25% of total costs. Those institutions whose indirect cost levels presently are 25% or less would not be affected by the reimbursement reduction. In cases where the reduction would be severe enough to cause an undue operational burden, a formula would be used to phase in the reduction over a two or three year period. The FY 1984 President's Budget assumes reductions of $72 million for NIH and $4 million for ADAMHA in indirect costs from levels they would otherwise attain under the current policy. According to preliminary estimates, the approach described here should accomplish the needed total reductions as equitably as possible.

CONSULTATION PROCESS

The issues associated with each of the policy options are complicated and controversial. It will be necessary to assess carefully the impact of any proposed change in the current reimbursement policy to ensure that it is as equitable as possible and that it takes into account the many differences among grantee institutions that contribute to varying levels of indirect costs.

Consistent with the Committee's intent, the DHHS has begun the process of consulting with representatives of research institutions for their views and concerns about each of the policy options described above. A PHS meeting with university officials and representatives of certain research societies was held on Thursday, February 17, 1983, at which the indirect cost problem was discussed and views exchanged. This dialogue will be continued with the purpose of developing practical short and long-term solutions to a mutual problem, including exploration of the feasibility and desirability of redefining reimbursable indirect costs (Long-term Option 1).

Attachment II to this report is a list of those who participated in the February 17 meeting and Attachments III and IV are papers expressing the views of some of the representatives of the awardee community.

Attachment I
2/23/83

TRENDS IN AVERAGE AMOUNT AWARDED FOR NIH TRADITIONAL RESEARCH PROJECT GRANTS (RO1)
FISCAL YEARS 1970-1982 IN TERMS OF 1970 DOLLARS

FISCAL YEAR	TOTAL COSTS - CONSTANT DOLLARS	DIRECT COST - CONSTANT DOLLARS	INDIRECT COSTS - CONSTANT DOLLARS
1970	$36,894	$28,740	$ 8,154
1971	39,497	30,395	9,102
1972	41,817	31,657	10,160
1973	42,272	31,561	10,711
1974	44,186	32,781	11,405
1975	40,890	30,242	10,648
1976	40,666	29,576	11,090
1977	42,394	30,757	11,637
1978	42,889	30,937	11,952
1979	42,243	30,204	12,039
1980	41,778	29,619	12,159
1981	41,651	29,271	12,380
1982	41,986	29,144	12,842

Note: Supplements to prior-year awards are excluded in the computation of the average dollars. Constant dollars are based on the biomedical R&D price deflators (FY 1970=100). The TQ is excluded. Unobligated balances are distributed between direct and indirect costs.

Attachment II

Participants at the Meeting on Indirect Costs Held
February 17, 1983, in the Hubert H. Humphrey Building, Washington, D.C.

Dr. John R. Hogness
President
Association of Academic
Health Centers

Dr. John F. Sherman
Vice President
Association of American
Medical Colleges

Dr. Lattie Coor
President
University of Vermont

Ms. Carol R. Scheman
Director of Federal Relations for
Health and Biomedical Research
Association of American
Universities

Dr. William Danforth
Chancellor
Washington University

Mr. Milton Goldberg
Executive Director
Council on Government Relations

Dr. John DiBiaggio
President
University of Connecticut

Dr. Frederico Welsch
President Elect, Association of
Independent Research Institutes, and
Budget Analyst, Delegation for Basic
Biomedical Research

Dr. Mary Jane Osborn
President
Federation of American Societies
for Experimental Biology

Dr. Robert Clodius
President
National Association of State
Universities and Land-Grant
Colleges

Dr. John A. D. Cooper
President
Association of American Medical
Colleges

Mr. Joseph Warner
Director, Contracts and Grants
Yale University

Dr. C. D. Cox
Chairman, Committee on Medical
Microbiology and Immunology,
Public and Scientific Affairs Board,
American Society for Microbiology

Dr. Linda Wilson
Associate Vice Chancellor
University of Illinois at Urbana

Dr. Robert Sproull
President and Chief Executive Officer
University of Rochester

Mr. Jerold Roschwalb
Director of Higher Education and
Governmental Relations
National Association of State
Universities and Land-Grant Colleges

Dr. Edward N. Brandt, Jr.
Assistant Secretary for Health

Dr. James F. Dickson III
Senior Advisor for Environmental
Affairs
Office of Assistant Secretary for
Health

Mr. Wilford J. Forbush
Deputy Assistant Secretary for
Operations
Office of Assistant Secretary for
Health

Dr. William E. Mayer
Administrator
Alcohol, Drug Abuse, and Mental Health
Administration

Dr. James B. Wyngaarden
Director
National Institutes of Health

Dr. Thomas E. Malone
Deputy Director
National Institutes of Health

Dr. William F. Raub
Deputy Director, Extramural
Research and Training
National Institutes of Health

Mr. Norman D. Mansfield
Director, Division of Financial
Management
National Institutes of Health

Mr. Robert L. Trachtenberg
Deputy Administrator
Alcohol, Drug Abuse, and Mental
Health Administration

March 3, 1983

Dr. James Wyngaarden
Director
National Institutes of Health
9000 Rockville Pike
Building #1, Room 124
Bethesda, MD 20205

Dear Dr. Wyngaarden:

Enclosed is a summary of the views that the Association of American Universities, American Council on Education and National Association of State Universities and Land-Grant Colleges, wish to have appended, on behalf of our members universities, to the National Institues of Health's response to Congress on the indirect cost issue.

We appreciate the opportunity to present our position, and hope we can continue to work together towards a resolution of these difficult issues.

Sincerely,

Robert M. Rosenzweig, President
Association of American Universities

Jack W. Peltason, President
American Council on Education

Robert L. Clodius, President
National Association of State
Universities and Land-Grant Colleges

On February 17, 1983, representatives of the Association of American Universities, the American Council on Education, and the National Association of State Universities and Land-Grant Colleges attended a meeting with other representatives of the higher education and biomedical research community and officials of the Public Health Service on the subject of indirect costs. Following this meeting, the university associations were invited to submit comments for the record to be forwarded to Office of Management and Budget (OMB) for inclusion in the Public Health Service's response to the request of the House Appropriations' Committee. The following is a summation of our views as presented at the meeting on February 17th.

INTRODUCTION:

The nation's biomedical research effort will be vitally important in the next five years. It will attract a great deal of attention from the public and from the Congress. The central items about which the Congress is likely to express concern are:

- Whether the research is sufficient for our nation's need,

- Whether it is of high enough quality and,

- Whether it is appropriately connected to, on the one hand, the productive sector of the economy which helps us to compete in world wide markets and, on the other, the practitioners who work to improve the health of the American people.

Our success in being able to fulfill our responsibilities will depend on strong academic institutions working in cooperation with a strong NIH for the purpose of supporting optimally those who do the real work, that is, the principal investigators and their research colleagues.

This relationship can be strained by continued disagreements over appropriate apportionment of research funds. Care must be taken to avoid such strain; equitable and mutually ageed upon resolution must be pursued by both the university research community and the Public Health Service.

It is well to remember that the Congressional mandate for a review of the issues surrounding indirect cost is:

> "The Committee is persuaded that indirect costs are a legitimate component of the costs incurred in performing biomedical research and should be adequately reimbursed. The Committee is also concerned by the widespread perception that federally sponsored research may be bearing more than its fair share of these costs . . . The Committee requests the Secretary of Health and Human Services, in cooperation with the NIH Director, to make a careful review of this matter, including consultation with the universities and other research organizations most directly affected and to submit a report setting forth conclusions and appropriate recommendations . . ." (Underline added.)

We who represent the heads of the institutions where most of the research is carried out believe that NIH has assumed wrongly that indirect costs of research have been rising faster than they should. The word "disproportionately" has been used and NIH has set about trying to rectify this wrongly perceived problem. We believe that research costs are the issue. Our job is better to understand the costs of research and the proper apportionment of these costs. We do not believe that indirect costs are rising disproportionately. On the contrary, we believe that monies for direct costs are not rising fast enough to meet the costs of inflation. We suspect that the deflator used by the NIH to express expenditures in constant dollars is too low. We take as evidence for this assumption the fact that the percent of the budget allocated to indirect costs has been rising.

It is not possible to decide this issue in time for this year's Congressional hearings. It is not right to budget decreased indirect cost reimbursement before Congressionally mandated consultation has taken place. It would be wrong to abrogate unilaterally the agreed upon principles of OMB Circular A-21.

As the Committee notes, indirect costs of research are legitimate research costs. We join the Committee in concern over the widespread perception that the federal government is bearing more than its share of these costs: it is this set of perceptions that we believe need careful study. We are aware of the rise in the rate of indirect costs and believe much, if not all of this increase can be explained and justified as legitimate costs of research. We are eager to join in efforts to explore further this increase, especially if such efforts can yield fruitful ways to control indirect cost expenditures.

At the invitation of Drs. Brandt and Wyngaarden we have joined in the beginning of what we hope will be continuing discussions of this issue. We appreciate being consulted by the National Institutes of Health and the Public Health Service as they seek answers to the complex set of questions about indirect costs and the appropriate federal investment in support of biomedical research. We have appended our response to the invitation from the PHS to discuss these matters.

FACTORS CONTRIBUTING TO THE PERCEPTION THAT THE FEDERAL GOVERNMENT IS PAYING MORE THAN ITS SHARE OF INDIRECT COSTS AND/OR THAT SUCH COSTS HAVE RISEN DISPROPORTIONATELY:

1. There is little awareness that both direct and indirect costs are essential to the performance of research. Direct costs are highly visible, while indirect costs are pooled costs that are not easily identifiable to an individual research project.

2. There are those who believe that indirect costs are reimbursed without review: Indirect costs are subject to the careful scrutiny, review, and approval or disapproval by federal auditors; such costs are allocated to cost pools by the institution and reimbursed by the federal government in accordance with federal guidelines.

3. There is failure to appreciate that indirect costs are truly research costs, and that without reimbursement for these costs the universities would be substantially weaker hosts to the nation's biomedical research: Research costs are divided between the direct and indirect categories only because there are some institution-wide expenditures incurred on behalf of all research activities that are charged as indirect costs for convenience and accounting purposes.

4. There are those who believe that indirect costs are general institutional funds, or that they support non-research activities such as teaching: Indirect costs at universities are divided into cost pools; teaching costs and other non-research costs are segregated from the cost pool designated for sponsored research.

5. There are those who believe that universities are reimbursed fully for direct and indirect costs of research: In fact, current federal cost principles are based upon mandatory university contribution to research costs.

6. There is a belief that universities do not have adequate incentives to control indirect cost expenditures since they are reimbursed by the federal government: The facts are, all indirect costs are shared between universities and the federal agencies that sponsor research; universities pay more than 1/2 of each dollar in the indirect cost category. Savings of this magnitude is more than adequate incentive to control costs.

7. The belief that indirect costs have risen disproportionately seems to be based upon the change in the average rate in the past ten years. There are a number of readily apparent reasons for this proportional increase:

- Direct costs of research have not kept pace with the cost of conducting research;
- Items in the indirect cost category (such as energy costs) have risen disproportionately;
- Prior to 1966, indirect costs were capped;

- Better management and improved identification of costs demanded by both the universities and the government has revealed that more costs must be appropriately allocated to research than earlier believed;

- The nature of biomedical research has changed: there is more equipment sharing, larger and more complex research teams, and therefore more pooled costs attributable to indirect cost categories.

NEXT STEPS

Congress has asked the DHHS to explore the perception that the federal government is paying more than its share of indirect costs. We believe it is vitally important to the nation's biomedical research enterprise and to the relationship between the research agencies and the universities to take this charge seriously, to explore these perceptions, and to reach conclusions in as timely a fashion as possible.

We believe there exists a set of questions in need of answers in order to deal responsibly and effectively with the perceptions about which the Committee has expressed concern:

1. Are there currently allowable costs, that should be excluded from federal reimbursement? If so, on what basis should they be excluded?

2. Are there economies and efficiencies which could be introduced, and at what cost to research productivity and/or accountability?

3. What are the principles that guide decisions about proportional share (as established first in 1947 and reiterated by Congress in 1976, these principles are: federally sponsored research shall leave the institution with no gain and no loss)? Should these principles change?

4. How do other performers, such as industry, deal with the reimbursement of indirect costs? Should universities be treated differently?

5. What are the cost factors involved in the increase in indirect cost rates?

We believe that the past few years have witnessed growing attempts to cut reimbursement of the direct and indirect costs of research. It is not possible to buy the same amount nor the same quality of research for less money. In fact there is good reason to believe that the total cost (direct and indirect) of top quality, cutting edge research, has gone up significantly for a wide variety of reasons. To ignore this increased cost is to harm the research effort, compromise the next generation of scholars, and erode this nation's leadership in biomedical research.

The existing government-wide policy of OMB Circular A-21 sets forth a process, and criteria for applicability, allowabilty, and cost analysis. We believe it is essential to understand the principles underlying A-21 before reaching any conclusion about indirect costs.

The nature of indirect costs has long been a controversial subject. We appeal to the Administration and the Congress to aide the community in establishing a coherent and logical process to seek resolution of differing views and to find whatever solutions make sense once perceptions can be refined into fact.

We believe that perceptions are substantiated more by the lack of good answers to critical questions than by the existence of any data.

As a first step in refining perceptions into facts, we propose :

The currently established group convened by the Assistant Secretary and Director of the National Institutes of Health be asked to examine:

1. Whether existing criteria for determining allowable cost of research are appropriate to biomedical research, or whether some special conditions attached to that research require different criteria?

2. Whether methods for apportioning costs among university functions and among research projects are fair?

If it is not possible to reach resolution within the context of the government wide principles of A-21, we believe the issues must be elevated to the Office of the President.

At this level, in order to reach resolution, the universities and the government must, a) agree on criteria, b) agree on apportionment and, c) agree that the new understandings will be implemented for all government agencies.

We remain ready to work with the PHS to reach resolution of these difficult issues.

Attachment IV

February 17, 1983

The attached preliminary document is presented herewith on behalf of the Delegation and the Association of Independent Research Institutes for purposes of todays discussion.

Sincerely,

Federico Welsch, M.D., Ph.D.

February 16, 1983

Dr. James Wyngaarden, Director
National Institutes of Health
Building 1, Room 124
Bethesda, Maryland 20205

Dear Dr. Wyngaarden:

Thank you for your invitation to attend the "indirect cost limitation" discussion on February 17, 1983, in Secretary Brandt's office.

The Delegation for Basic Biomedical Research (DBBR) and the Association of Independent Research Institutes (AIRI) have long been concerned with:

a) the erosion of NIH's purchasing power because of insufficient appropriations to

compensate for the direct and indirect cost components of the biomedical R&D deflator, and

b) the faster increase of the indirect cost component - both at NIH and at extramural institutions* - when compared with the rate of increase of the direct cost component of biomedical research.

The faster rise in the indirect cost component is mainly attributable to:

1) Study section and NIH administrative cuts in direct costs and institutional decisions to hold back on recruiting, since these actions increase the indirect cost rate.

2) unusually high energy costs during the 70's

3) increase in federally mandated "accountability" requirements to fulfill fiscal, social or other desirable purposes but which do not promote the acquisition of new scientific knowledge.

4) no incentives for institutions to keep their indirect costs down.

We agree with you that the time for action - to contain both further reductions in funds

*Indirect costs at the NIH itself (the sum of Direct Operations, Program Management and Office of the Director in the NIH budget) have increased 856% from 26.1 million or 2.4% of the total NIH budget of 1.1 billion in FY1968, to 212.5 million or 5.8% of 3.6 billion in FY1982. During the same time extramural indirect costs have increased 719% from some 96 million or 19.1% of the extramural budget of 503 million to 690 million or 30% of an extramural budget of 2,301 million. Since the Intramural Research program has remained more or less constant as a portion (12%) of the total NIH budget, the increased indirect costs of both the NIH and extramural communities have been essentially absorbed by the direct cost available to the extramural program. It is to the credit of the NIH, Administration and Congress that by striving for the stability in the number of project grants the investigator-initiated mechanism has been protected as much as it has.

for the direct support of research and further escalation in indirect costs - is now. Our top priority must remain 5,000 investigator initiated competing grants to be awarded each year without cutting the average amount of the awards, and with full reimbursement of allowable indirect costs.

In an attempt to find a long term solution I propose the adoption of policy option #4 for a three year period, retroactive to October 1, 1982 (for example, fixing the indirect cost/total cost ratio based on the experience of the last three years of finalized rates) with instructions to research institutions that over that period of time (a) they are not allowed to shift cost centers from indirect to direct costs and (b) they can not expect to receive any adjustments based on new final rates. If circulars A-21 and A-22 could be modified by the Administration (as suggested in policy option #2) during the next 18 months then redefined and standarized (as in option #5) reimbursable indirect costs could be negotiated during the following 12 months. Implementation of the new rates (now including shifting where appropriate) could then be done for FY1986.

The above proposal would save only a fraction of the 72 million reduction in indirect costs foreseen in the President's 1984 budget for the NIH, but would preserve the health of research institutions* and produce

*My institution, for example, already cost-shares with the NIH to an extent of approximately 10%, by supporting the direct and indirect costs of research for new recruitees, until they can get funding on their own. Options 1 (an across the board reduction in reimbursement of allowable indirect costs) or 3 (establishment of a standard fixed allowance), if implemented hastily, could sink this single purposed research institution.

the desired effects in 1986. With the required additional appropriations for 1984 and 1985 it would not affect our investigators.

Thank you again for letting me share my views with you.

~~Sincerely,~~

Federico

Federico Welsch, M.D., Ph.D.
President Elect, AIRI
and
Budget Analyst, DBBR

PAY COSTS

Senator RUDMAN. Turning to pay costs, Dr. Mayer——

Dr. MAYER. Yes.

Senator RUDMAN [continuing]. Apart from St. Elizabeths, your budget indicates $1,985,000 in 1983 pay costs. I always have to look at these figures closely because most of my time is on the Defense Appropriation Committee.

Dr. MAYER. This is so small.

Senator RUDMAN. I have tended to read that as $1 billion.

Dr. MAYER. Please be careful.

Senator RUDMAN. That is $1,985,000 in 1983 pay costs to be met by transferring appropriated funds. And of this amount $1,405,000 will be transferred from the mental health clinical training program, $375,000 from drug abuse research, and $203,000 from alcoholism research.

Would you indicate the effects of each of these reductions and explain why you are decreasing research in fiscal year 1983 when your 1984 budget proposes substantial increases?

Dr. MAYER. We have had to try to accommodate to our mandated pay raises within our existing budget. Consequently, we took a large amount out of clinical training because that was planned for phaseout by the administration.

The impact was to reduce the amount of clinical training we could do, but not substantially. The erosion of both drug abuse and alcohol research, in order to help pay for those costs, was simply a sacrifice that we had to make.

We continue to wish to expand our research, as I indicated in my opening statement, and will continue to budget for that purpose. But when faced with the fact that we must come up with the money to pay the congressionally mandated pay raises of employees and we have a finite amount of money in our budget, we have to make choices.

We have used a similar solution in previous years. It has been modified from time to time, depending on what was available, taking other money out of research and clinical training and always absorbing some direct operations in order to fund these costs.

RESEARCH TRAINING

Senator RUDMAN. The budget for research training proposes an increase of less than $400,000, from $17,337,000 in fiscal year 1983, to $17,702,000 in 1984. The justification indicates that this is sufficient to maintain the number of trainees at 1,000.

Given the fact that you are committing to a 15-percent increase in research funds, should we not also be thinking of increasing the number of researchers?

Dr. MAYER. Yes; perhaps, we should. So far, there has been a sufficient pool of researchers to provide us with an increasing number of applications of good quality for research grants. If the field continues to expand at the rate at which it is presently expanding and continues to attract more and more public and scientific attention, then it is altogether possible that the day will come, perhaps not far off, when we

will need to make some additional effort to train researchers for these fields.

Apparently, we have attracted enough researchers from other biomedical fields into these exciting new areas to provide us with a high number of high-quality applications at this time.

But inasmuch as it takes from 5 to 8 years to train a researcher, I think that very soon, we will probably be led to the conclusion that there should be an increase in the number of research trainees that we support. We did not find that to be true this year.

CLINICAL TRAINING

Senator RUDMAN. The proposal you have in the budget is to terminate all Federal support for clinical training in the mental health professions—a cut of $20.1 million.

Dr. MAYER. Yes.

Senator RUDMAN. Is it your contention that the program has accomplished its aims, and there are no shortages at this time?

Dr. MAYER. Yes and no. Yes; it has accomplished its aims to a very considerable extent. What is not generally recognized is that about 25 years ago, there were only a very few thousand psychiatrists, psychologists, psychiatric nurses, and social workers in this country. There are today, partly because of investments by the Federal Government, more than 30,000 practicing psychiatrists, more than 31,000 clinical psychologists, and in excess of 100,000 social workers.

The Graduate Medical Education National Advisory Committee has asserted that this is still not enough people in these fields. That is an assertion with which some would take some exception or at least question. We don't know; nobody knows for sure if that is enough people.

We do know we are short of people in mental health, as well as substance abuse and alcoholism, who focus their attention on the elderly, on children, and on some minority groups. Those shortages were noted by the Congress last year in specifying ways that they wanted us to invest the clinical training funds which they gave us. We followed those instructions very carefully, both last year and this year.

So I can't assert that there are plenty of all these people, and we are just fine forever. But given the need at this point to reestablish a very stable funding base for our research, the need to exploit the tremendous breakthroughs that have occurred just in the last few years—things like being able to transplant part of a brain and have it function and even parts of other organ tissue and have it function in the brain—these demand that our principal emphasis be on research.

Furthermore, our Federal contribution to the total clinical training effort in these fields in the United States was only a small percent of the total national effort. So what has developed over these last 20 years has been a tremendously increased capacity on the parts of States and the universities themselves to support a training enterprise that didn't exist in large numbers 25, 30 years ago.

So it is less a matter of shortages than of priorities.

NIH MANAGEMENT FUND

Senator RUDMAN. We just have a few more questions, then we will turn to your testimony on St. Elizabeths.

Talking about NIH charges, since we have been talking about overhead, the budget proposes $22,105,000 for the NIH management fund, an increase of 10 percent over last year.

We understand that offsets the cost to NIH of providing administrative support for your intramural research.

Dr. MAYER. Basically.

Senator RUDMAN. I wonder if you question the proposed 10-percent increase since your intramural research program will increase by only 3 percent in fiscal year 1984 from $64.4 to $66.8 million.

One of the reasons that has been cited for the need to control the indirect costs of research performed by the universities is excessive administrative costs. Yet, from our calculations, NIH charges you $22 million for administrative support for a research program of $66.8 million. That is roughly a 33-percent overhead factor for your intramural research budget.

Do you think that is fair charge back? And in light of that, is it fair to say the universities are charging too much?

You are between a rock and a hard place.

Dr. MAYER. We complain about it when appropriate.

Senator RUDMAN. Without any results.

Dr. MAYER. Well, no, because I think it is totally justified. NIH, after all, is a sister agency of the Public Health Service and we think they treat us very fairly. In any case, the management fund that we contribute to at NIH is not a simple ratio relationship to the total investment in our intramural research, because part of our intramural research doesn't even go on there. The entire drug abuse intramural program is located elsewhere as is the nonclinical portion of the alcohol program.

Furthermore, these aren't just administrative costs; there is engineering, procurement, building maintenance, and most significantly clinical support services including the around the clock supply of properly qualified nurses to monitor our patient beds.

Senator RUDMAN. So some of those are direct labor costs?

Dr. MAYER. Oh, absolutely. So it is high, Senator, but we think it is fair.

Senator RUDMAN. I think probably it would be beneficial if we did provide for the record a breakdown of that charge, of the charges, administrative support, charged back by NIH. Could you do that?

Mr. ITTEILAG. Yes, sir, we would be happy to do that.

[The information follows:]

NIH MANAGEMENT FUND 1984 DISTRIBUTION

ADAMHA maintains laboratory and office facilities within NIH Buildings, 9, 10, 15K, 31, 32A, 36, and the NIH Animal Center. Within Building 10, the NIH Clinical Center, ADAMHA maintains 79 research beds (69 for NIMH, 10 for NIAAA). To this end, ADAMHA utilizes the research and administrative support services provided by the NIH Divisions of Administrative Services, Engineering Services, Research Grants, Research and Safety Services, and the Clinical Center. Each of the organizations is

financed through the NIH management fund. The NIH management fund was established to facilitate the conduct of NIH operations financed by two or more appropriations. Fund activities are financed primarily from advances and reimbursements from the several institutes. Formulas for determining each institute's contribution reflect usage of services provided by the fund. The following services are to be provided to ADAMHA in 1984 at the cost estimates shown; they are slightly less than the figures in the budget because they exclude funds for accounting and auditing services, paid separately to NIH.

	Cost estimate	
Cost center	NIAAA	NIMH
Administrative Services	$56,000	$853,000

Includes transportation (passenger shuttle services, mail and messenger services, motor pool services, moving and hauling functions), sanitation, (housekeeping, pest control, laundry pickup, and the disposal of glassware, animal waste, and trash), and miscellaneous administrative services, (passport and visa services, central travel services, space and telecommunications management services, and audio visual and conference room services).

	Cost estimate	
Cost center	NIAAA	NIMH
Clinical Services	$1,737,000	$11,952,000

Includes 79 research beds within the Clinical Center. The Clinical Center provides all appropriate and necessary clinical and hospital support services required to sustain these research beds. These include basic inpatient hospital services such as critical care, nursing, pathology, radiology, pharmacy, nutrition, and rehabilitation services; and a full range of hospital support services such as material/suppy management, fabric care, medical records, and patient welfare.

	Cost estimate	
Cost center	NIAAA	NIMH
Engineering Services	$198,000	$2,978,000

Includes plant maintenance services (maintenance of grounds; snow removal; routine maintenance and major repairs to the supply and exhaust air system, steam, water (tap, distilled, deionized), lights, cold rooms, and mechanical freezers; utility services such as electricity, water, gas, fuel oil, diesel oil, deionized water, and sewage treatment; planning for renovations, construction projects, and major repairs; and in-house labor), engineering design services, and construction engineering services.

	Cost estimate	
Cost center	NIAAA	NIMH
Grant Review Services (Extramural only)		$1,497,000

Includes receipt and distribution of grant aplications, grant referral and review, IMPAC and CRISP file maintenance and reporting services on both a routine and an as needed basis.

	Cost estimate	
Cost center	NIAAA	NIMH
Research Services	$40,000	$1,089,000

Includes surgical and recovery services for research animals; technical advice and services on pathology problems pertinent to research animals; technical advice on the

need for, design, and the acquisition of scientific equipment; a source for scientific reading material, reference bibliographic services, and translation services (except for contract translation billed direct); and technical advice and consultation on environmental controls, water problems, biological hazards, glasswashing, and sterilization problems.

Cost center	Cost estimate	
	NIAAA	NIMH
Protection and Safety Management Services	$28,000	$773,000

Includes protection of persons, property and facilities through the NIH special plice force; enforcement of parking and traffic regulations and maintaining 24-hour security patrol; detective services, locksmith services, parking areas, and contro parking permits; and maintenance of fire equipment within buidings, dispose of chemicals, and emergency fire, and rescue services.

Total	$2,059,000	$19,152,000

CLOSING REMARKS

Senator RUDMAN. We have several other questions for the record, and we will submit those to you.

Dr. MAYER. Fine. Be glad to answer them.

Senator RUDMAN. You will send them back to us with the other questions.

Dr. Mayer, I understand you wear another hat this morning. Would you like to proceed on your request for St. Elizabeths with a brief summary of your statement? And we will again include your other statement on the record.

Dr. MAYER. Thank you, Senator.

I would like to ask Dr. William Dobbs, the Superintendent of St. Elizabeths, to take Dr. Pollin's chair.

This is Dr. Dobbs, Senator Rudman.

Senator RUDMAN. Glad to have you.

OPENING REMARKS

Dr. MAYER. St. Elizabeths, a major mental health hospital in this country, is a part of the National Institute of Mental Health. I have very little as an opening statement to make about St. Elizabeths except to say that this is a very precious national resource which has changed markedly over the years, partly because of advances in community mental health, partly because of the fact that there have been changes within the District itself in their government.

It is a major budget item for us. And it has been noted for some years that the proportion of patients at St. Elizabeths who are not properly Federal responsibilities, but are simply residents of the District of Columbia, that the proportion of such patients at St. Elizabeths has risen to where they now constitute fully 90 percent of all the patients out there.

On the other hand, there has been a cap imposed on the District's contribution to the cost of operating that hospital, roughly $25 million out of a total cost of $132 million or less than 20 percent even though 90 percent of the patients are D.C. residents.

This has caused some concern, obviously, because what it means is that the people of the rest of the United States are subsidizing the care of the District's patients within that hospital, which they do for no other geographic or geopolitical entity.

So a plan has been devised whereby the District contribution to the support of the hospital would steadily increase over a period of 10 years until they assume full responsibility. This is unquestionably a difficult thing for the District to do. And yet, we are trying to work with them closely to assist them and encourage them further to develop their community program so they can accept patients from the hospital and reduce the occupancy of that hospital.

PAY COSTS

Senator RUDMAN. Mr. Itteilag, I want to direct the first question to you.

Information we have indicates that total increased pay costs for fiscal year 1983 for the hospital are $5.9 million, all of which would be taken from the rural development loan fund rather than provided by a supplemental.

My question is simply this: Since I am sure this is a departmental policy, not a policy made by Dr. Mayer, why was the decision made to fund this pay raise through the rural development loan fund?

The reason I ask the question is because a similar proposal was made by the administration last year and rejected by the Congress. I wonder why you went ahead and did this again. I'm sure you didn't make the decision; you must know why somebody made the decision. And would you like to tell us or maybe we will get that somebody down here, and they can tell us.

Mr. ITTEILAG. Senator, as a matter of policy with the administration, we had a goal of attempting to absorb within existing appropriation resources about 50 percent of the pay raise that was effective last October. Therefore, we looked for existing resources which we didn't believe were going to be used for other purposes or we didn't believe the purposes for which they were going to be used were as high a priority as having to meet the demand for a pay raise.

And, therefore, among other sources, we believe there are sufficient assets in the rural development loan fund that are not going to be used and that could be devoted to offsetting part of the pay raise within various accounts of the Department.

Senator RUDMAN. Plus the real question as to whether or not they are going to be used. $20,251,000 is proposed for transfers. The balance is $11,800,000 Food and Drug Administration and a small amount to Health Resources and Service Administration.

I assume you will be hearing again on a different attitude about that from the Congress.

Mr. ITTEILAG. We understand, Senator, the interests of the committee as expressed in report language to us last year.

I would point out that there was at the end of fiscal year 1982 more than $28 million unobligated in this particular fund. And we believe it

is possible to use a portion of that money for the pay raise and also carry out the committee's direction with respect to making additional loans or loan guarantees with the assets of that fund.

Senator RUDMAN. Well, of course, we have been going back and forth on this now for a couple of years. And I guess maybe our use of the language is not literate enough in the report. I think maybe this year, we will sit down and try to write it in a No. 1, 2, 3, 4, style. And maybe people will finally get the message.

But I don't want to berate you, Mr. Itteilag; it is not your decision. But we get kind of tired of going over the same thing over and over and over again. The report language, as I remember it, had some rather specific directions as to what to do with that.

At any rate, I don't think we ought to kill the messenger that brings the bad news so we will just go on from there.

D.C. REIMBURSEMENT SHORTFALL

Dr. Mayer, it has come to our attention that the request submitted by OMB on behalf of the D.C. government is only $29.5 million with a potential $25 million shortfall in funds requested for operation of the hospital.

Can you tell us how that discrepancy arose since both your budget and the D.C. budget are submitted to OMB?

Dr. MAYER. They are not submitted jointly, unfortunately. The District budget was submitted after we finalized the proposed increase in the District's contribution for the care of their patients. I am unaware of how their budget review was handled by the OMB.

LEGISLATIVE PROPOSAL

Senator RUDMAN. Now, there is a proposal to establish a private nonprofit corporation to run St. Elizabeths. What is the status of that legislative proposal? The budget assumes an enactment as of August 1 of this year.

I wonder why there is a delay on submission of that proposal.

Dr. MAYER. Developing a private, nonprofit corporation proposal that would meet everybody's interests and protect everybody's interests, beginning with the patients, of course, has been a very complex matter. We understand on very good authority that the proposal, which has been under very careful scrutiny by the Office of Management and Budget, is about ready to submit to the Congress. And, it is true, we hope for and anticipate the enactment of the legislation by mid-point or three-fourths of the way through fiscal 1984.

POSITIONS AND COMPENSABLE WORK-YEARS

Senator RUDMAN. I asked the question because it is related, of course, to some of the numbers in this submission. There were reductions of 283 full-time positions, another 350 compensable work-years in their submission. That constitutes a reduction in excess of 18 percent.

That raises a couple of questions. How much of this reduction is associated with the proposal to establish a nonprofit corporation to run

the hospital? And why is it assumed that—that is, if I am correct in that that is the assumption—why do you think the corporation could run the hospital with that many fewer employees?

I am not saying you can't, but I am asking you what makes you think that?

Dr. MAYER. The reduction of 283 is not related to the corporation proposal.

Senator RUDMAN. What is it related to?

Dr. MAYER. That is being made to bring budgeted positions in line with the actual staffing patterns that exist out there now. So it wouldn't result in a reduction in force.

Senator RUDMAN. The 350 compensable work-years is related though, is it not?

Dr. MAYER. Yes; but the reason for the lower number of compensable work-years in our budget is that we believe the corporation can be in place by the fourth quarter of fiscal 1984. And that would cease the Federal status of these employees along with their accounting of compensable work-years. So it reflects the number of work-years with which we could adequately run the hospital until the fourth quarter of fiscal 1984.

Obviously, if there are major interferences with that legislation and with establishing a corporation, we will have to make an adjustment. And we will have to discuss how at that point.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator RUDMAN. We have some other questions for the record we will submit to you.

And we are going to have the subcommittee stand in recess for a few moments, awaiting the arrival of the chairman of the full committee. Senator Hatfield is going to conduct the balance of the meeting this morning. So let's have a short recess.

Dr. MAYER. Thank you very much.

[A brief recess was taken.]

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

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Questions Submitted by the Subcommittee

COST TO SOCIETY OF ADM PROBLEMS

Question: Dr. Mayer, in your prepared testimony you state that alcohol, drug abuse and mental health problems are estimated to have cost our nation $106 billion in 1977. This would seem to indicate that our estimates are seven years out of date. Don't we have more recent figures and if not, why not?

Answer: We do not have more recent accurate estimates of the cost to society of alcohol, drug abuse, and mental health problems than the estimates you have cited for 1977, but I am directing that an updated study be initiated in the very near future. The reason we do not have more recent figures is that these estimates are based upon complex methodologies that draw upon a wide variety of data, many of which are not collected annually. As a result, the investigators must select the most recent year for which all the necessary data are available. In the case of this particular study, the investigators began to do the study in 1979-80 and made use of data from 1977. Their report was completed in 1981 and submitted to us in final form at the end of 1981. Although the data are six years old, the report itself has been available for less than two years. We believe this is one of the most careful studies of health costs to the nation and we intend to build upon its careful methodology to update these figures in the very near future. Future studies may be easier to do since they will be able to make use of the methodology already developed. I hope, also, that future studies will permit more rapid and regular updates.

BLOCK GRANT FUND DISTRIBUTION

Question: During consideration of the emergency supplemental it was brought to our attention that the distribution of funds within each State for the three programs may differ substantially. Have you found a disproportionate balance in some States between the funding of alcohol, drug abuse and mental health programs as a result of the application of the block grant formulas? If so, please explain.

Answer: The block grant legislation attempts to maintain the relative program proportions by requiring that States spend about the same percentage in mental health versus substance abuse areas as they spent in the base year, which is 1981 for mental health and 1980 for drug abuse and alcoholism. The States were required to maintain these ratios exactly in 1982 but have a five percent discretionary leeway in 1983. Therefore, while it is true that the relative ratio of mental health to substance abuse varies widely among the States, in each State it closely approximates the proportion of Federal investment actually realized before block grants were implemented. The fact that the percentage of discretionary funding increases in future years will permit each State to shift money into those programs areas it deems necessary to expand. This State discretion is the basis of the block grant concept.

In several States we have noticed some small shifting of funds within the substance abuse area, within the legislative

limitations. Generally this has been a reduction in drug abuse and an increase in alcohol expenditures as allowed by the 30 percent discretionary component of substance abuse funds. This type of movement was envisioned by Congress in devising the formula and permits the States to adjust their program mix to more effectively respond to local needs.

STATE BLOCK GRANT COMPLIANCE REVIEWS

Question: What investigations has the Secretary conducted on the use of funds under this block grant to evaluate their compliance with the requirements of the block? What States have been investigated?

Answer: In FY 1982 the Department completed five State compliance reviews concerning the implementation of the Alcohol and Drug Abuse and Mental Health Services Block Grant. The reviews were held to evaluate the State compliance with the legislative requirements of the block and were conducted in each State's offices over a two or three day period. Reviews were held in Georgia, Minnesota, New Mexico, Oregon, and Rhode Island.

States were selected for possible review after consideration of such factors as geographic distribution, State size, urban or rural character and other Federal/State involvement presently underway, e.g., GAO audit. After the specific dates were established, guidelines for the reviews were sent to the States. The reviews were conducted by having State-selected officials discuss the actions they have taken to ensure compliance and by reviewing various State documents that related to the State's compliance with the statutory provisions. As a component of the reviews, the States were provided feedback concerning their adherence to the identified statutory provisions and how they were using the block grant funds.

In FY 1983 ten State compliance reviews are scheduled. As of June 30, reviews were completed in Arizona, Nebraska, North Carolina, North Dakota, and Oklahoma. Five more compliance reviews are scheduled for Alaska, Connecticut, Michigan, New York, and Virginia.

In addition to the State compliance reviews, the Secretary, in response to a request from Congressman Henry Waxman, has initiated an Inspector General Audit in Nevada. This audit is currently underway and is investigating complaints that the State used Federal funds to supplant State funds and that a public hearing was not held on the intended use of the funds.

Copies of the completed State compliance review reports are available for individuals interested in the results of the investigations. A copy of the Inspector General Audit report will be made a part of the official grant file.

BLOCK GRANT DATA

Question: What kind of data are States required to report on numbers of persons served and types of services provided by programs under the Alcohol, Drug Abuse, and Mental Health Block Grant? What kinds of data of this type would you like to see

reported in order to maintain statistics on the incidence and treatment of alcohol, drug abuse and mental health problems?

Answer: States are provided substantial discretion in preparing block grant applications, plans and reports. Regarding data on persons served and services provided, the States, in their applications for ADMS block grant funds, must certify that they have identified those populations, areas, and localities in the State with a need for mental health, alcohol abuse and alcoholism, and drug abuse services and must describe the programs, activities, and services to be provided. States receiving ADMS block grant funds are also required to submit an annual report on ADM block grant activities. These reports must meet the requirements of the block grant statutes. Annual reports must contain such information as may be necessary to determine how funds were spent, what activities were supported, who received the funds, a statement of the purposes for which the funds were spent and whether these purposes were consistent with needs identified in the application, and whether progress was made toward meeting those needs.

Given the legislative mandate, adequate statistics can be maintained with these data.

BLOCK GRANT ALLOTMENTS AND PREVENTION AND OTHER PROGRAMS.

Questions: Are States allocating their ADAMHA Block Grant allotments among alcohol and drug abuse and mental health programs as required by law? What kinds of prevention and early intervention programs are States supporting with 20 percent of their substance abuse funds?

Answer: All States assured us in their applications that they would allocate their block grant funds as required by the law. We have not, however, as yet received detailed reports, e.g., the audits, confirming these allocations.

The States are reportedly supporting a wide variety of alcohol and drug information, education, early intervention and prevention programs with the required 20 percent of their substance abuse funds. These efforts are targeted to such groups as drinking drivers, children, youth, women, the elderly, the general public, the occupational force, pregnant woman and ethnic populations. Specific examples include establishing employee assistance programs aimed at identifying troubled employees; providing diagnostic services, education and outreach to assist employees with problems which disturb job performance; developing alternative programs--e.g., activities which help young people find meaningful roles and experiences in life such that drug abuse becomes unattractive and incompatible with strivings, growth and accomplishments; identifying cost effective drug abuse intervention/prevention strategies/programs; meeting emerging needs for substance abuse prevention; and strengthening/enhancing the efforts of parent groups concerned with the substance abuse issues confronting today's children and youth.

BLOCK GRANT FUND TRANSFERS

Question: Which States transferred funds from their Alcohol, Drug Abuse, and Mental Health Block Grant allotment to other block grant activities?

Answer: At this time, based on the information we currently have available from approximately 30 State annual reports for FY 1982, we understand that the State of Georgia and the District of Columbia have transferred funds from their ADMS block grant allotment to Maternal and Child Health Services block grant activities.

COMMUNITY MENTAL HEALTH CENTERS DEFUNDING

Question: Which States, if any have defunded any community mental health centers under block grant funds and for what reasons?

Answers: No States have so far been given approval by the Secretary to defund any community mental health center under the block grant. We do, however, have preliminary indications that one State is considering such an action. We will be pleased to share that information with you when we receive official notification.

STATE ADMINISTRATION OF BLOCK GRANTS

Question: What States have assumed the administration of the Alcohol, Drug Abuse, and Mental Health Block Grants?

Answer: During FY 1982, all 57 States and Territories applied for and were awarded their ADAMHA block grants, thereby assuming the responsibility for administration of this program.

GRANTS TO INDIAN TRIBES

Question: Which Indian Tribes applied directly for ADAMHA Block Grants? Have their applications been approved?

Answer: In 1983, the agency received applications for block grant awards from the Phoenix Service Unit Indian Health Board in Arizona, the Red Lake Band of Chippawa Indians in Minnesota, the Confederated Salish and Kootenai Tribes of Flathead Reservation in Montana, and the Oglala Sioux Tribe in South Dakota. All four applications were approved and the block grant awards have been made.

ALCOHOLISM AND DRUG ABUSE REDUCTION GOALS

Question: Do you have any targets to shoot at in reducing alcoholism and drug abuse? What goals have you set yourself?

Answer: The National Institute on Aclohol Abuse and Alcoholism has, as part of the Department's prevention goals for 1990, specific objectives for (1) increasing the level of awareness of health risks associated with alcohol aubse; (2) reduction in mortality and morbidity associated with alcohol abuse; and (3) prevention of any increase in the levels of alcohol use. Primary among these objectives are those to reduce the proportion of adolescents with acute drinking related problems by 10 percent, to reduce cirrhosis mortality by 15 percent, to reduce the incidence of the fetal alcohol syndrome by 25 percent, and to reduce fatalities involving drunk drivers by 20 percent.

The goal of the National Institute on Drug Abuse, as stated in the Federal Strategy for Prevention of Drug Abuse and Drug trafficking, is "to reduce the level of drug use among all Americans, but especially among school-age children for they are the future of our country. A specific objective is to reduce the daily use of drugs by 30 percent as measured by the 1984 NIDA High School Senior Survey."

In both the alcoholism and drug abuse areas we of course have numerous other goals involving prevention and substance abuse reduction which we have not quantified, but which we are avidly pursuing.

CONSULTANTS IN THE NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

Question: What use does the National Institute on Alcohol Abuse and Alcoholism make of consultants in its operations?

Answer: The National Institute on Alcohol Abuse and Alcoholism utilizes consultants, through the contract mechanism as well as through appointive consultants, to gain non-Federal expertise. It is estimated that $1.1 million, or 2 percent of the Institute's budget will be used for consultant services in FY 1984.

Question: What functions do they perform that could not be performed by your employees?

Answer: Consultant services are utilized by the Institute to provide the necessary interchange of scientific information, the development of consensus on research and policy issues, and the dissemination of research information. The use of non-Federal expertise for these purposes, through conferences and workshops, allows for a more comprehensive and cost-effective research effort, and helps to assure that new knowledge will be utilized in the services delivery system. Consultants are also required to provide peer-review of research and research training grant applications, and to serve on the National Council on Alcohol Abuse and Alcoholism. In addition, non-Federal expertise will be needed in FY 1984 to assist in the development of a public education campaign targeted to teenagers.

STATUS OF THE NATIONAL CLEARINGHOUSE FOR ALCOHOL INFORMATION

Question: What is the status of the National Clearinghouse for Alcohol Information?

Answer: The National Clearinghouse for Alcohol Information continues to be the Institute's major channel for disseminating alcohol information to researchers, services delivery personnel, and the general public. The Clearinghouse responds to approximately 10,000 requests for information each month. In addition to collecting, storing and disseminating information, the Clearinghouse is actively involved in the development of educational materials for health professionals and in outreach efforts to encourage and assist the prevention activities of State, local and voluntary organizations.

Question: Is it still in operation or is it slated for phase-out as was the Mental Health Clearinghouse?

Answer: The Clearinghouse is considered a vital part of the Institute's program and there are no plans to phase-out this effort, although the annualized level of the Clearinghouse activities were reduced by 32 percent in FY 1982. A new contract will be let in FY 1984 to continue its basic operations at the FY 1982 level. However, an additional $500,000 will be added to implement part of the Secretary's Teenage Alcohol Initiative. This increase will strengthen the Clearinghouse's capability for disseminating information to States and communities and mobilizing private resources in prevention programs targeted to teenagers.

ALCOHOL RESEARCH AND TRAINING EVALUATION

Question: Does the National Institute on Alcohol Abuse and Alcoholism (NIAAA) perform any evaluations of its research and training programs?

Answer: The National Institute on Alcohol Abuse and Alcoholism performs the following evaluation of its research and training programs. In FY 1983, the NIAAA Research Planning Panel reviewed the Institute's entire research portfolio and is in the process of making recommendations with respect to research needs and unmet research opportunities. Also in FY 1983, an evaluation of the NIAAA Alcohol Research Centers during the first 5 year period (1977-1982) of the program and the Intramural Research Program Evaluation which evaluates scientists and their research productivity through the establishment of a Board of Scientific Counselors are taking place. These evaluation projects are being conducted in-house or with a small contract dollar amount. The Institute is in the process of developing a preliminary FY 1984 evaluation plan. Some projects under consideration are: research conferences on alcohol and neuropsychological grant dysfunction, state of knowledge of specific treatment research issues, alcohol-derived physical brain injury, research advances in family focused therapies, and finally, prostaglandins and alcoholism. Other research and training evaluation projects may be developed in the evaluation planning cycle for FY 1984.

Question: How is such an evaluation carried out?

Answer: Evaluation activities are carried out through a variety of mechanisms including contracts, purchase orders, and NIAAA in-house evaluations. All the evaluation projects are coordinated through an annual Institute Evaluation Plan consisting of a brief description of each of the evaluation projects. A specific office coordinates all the evaluation activities within the Institute, and works with the Office of the Administrator, the other Institutes, and other PHS levels to ensure appropriate and timely evaluation projects.

Question: What percentage of the NIAAA budget is spent on evaluations?

Answer: Approximately one percent of the NIAAA FY 1983 and 1984 budgets will be spent on evaluation as authorized under the Public Health Service Act. Evaluation is an intregal part of the

Institute, and in addition to the one percent set aside, many evaluation projects occur in-house.

ALCOHOLISM RESEARCH PRIORITIES

Question: What priorities have you established for alcoholism research in FY 1984? How are such priorities determined?

Answer: Alcohol research priorities for FY 1984 are: (1) research aimed at the prevention of alcohol problems among teenagers; (2) identification of risk factors for alcohol problems, including biochemical and physiological traits as well as familial and cultural factors; (3) development of improved methods for early identification of individuals with alcohol problems: (4) research on fetal effects, including the effects of moderate drinking during pregnancy; (5) research into the reversibility of the damaging effects of chronic alcohol use on the central nervous system; (6) development of improved treatment approaches and methods for assessing new and existing treatments; (7) prevention research, including studies of the effects of changes in laws and policies on alcohol problems; and (8) epidemiologic research on the incidence and prevalence of alcohol problems.

These priorities are in general based on the Institute's best judgment regarding research needs and opportunities for productive research. In determining the priorities, the Institute has drawn on the knowledge of non-Federal scientists through informal consultations, a 1980 report on research opportunities by the Institute of Medicine of the National Academy of Sciences, and through convening conferences to examine specific research areas. In planning for FY 1984, the Institute has also taken into account the special research needs associated with the Department's health promotion objectives for 1990 and the Secretary's special initiative for prevention of teenage alcohol abuse.

RESEARCH ON ALCOHOL PROBLEMS AMONG YOUTH

Question: What research on alcoholism and alcohol abuse problems among young people does the Institute support?

Answer: Ongoing research is examining a range of genetic, familial, environmental and developmental factors in relation to alcohol problems among young people. Research includes the study of problem development in children of alcoholics. Such research is needed to provide a basis for intervention strategies targeted to these high-risk families. Other research is providing a follow-up on data collected from school-age young people ten years ago to provide a better understanding of the persistence of adolescent problem behavior into adulthood. Other research is looking at the impact of legislation that raises the minimum legal drinking age on teenage drinking and traffic fatalities.

The Institute is seeking to expand research in FY 1984 into the problems of alcohol abuse among young people, with a special emphasis on research to develop improved prevention strategies.

ALCOHOL RESEARCH CENTERS

Question: How many alcohol research centers will we fund in FY 1984? What level of support will they receive? How does the research they perform differ from the research performed in the National Institute on Alcohol Abuse and Alcoholism's own intramural laboratories?

Answer: It is estimated that ten National Alcohol Research Centers will be funded in FY 1984 for a total of $10 million. While the Institute's intramural research program provides long-term funding stability, enabling scientists to undertake long-term projects not possible within the extramural program, the Centers allow for multidisciplinary research, utilizing outstanding research talent throughout the country which is available only through the extramural program. We believe that only through a multi-faceted approach which utilizes research centers, individual project grants and the intramural laboratories, can we achieve the critical mass of research activitiy required for optimum results.

PREVENTION RESEARCH

Question: What kinds of research in prevention of alcoholism and alcohol abuse do we support?

Answer: The National Institute on Alcohol Abuse and Alcoholism is placing increased emphasis on prevention research. In order to stimulate prevention research applications, a revised research grant announcement emphasizing prevention research was sent to the field November 1982. In preparation for a new Prevention Research Center, to be awarded late in FY 1983, a special program announcement was disseminated in January 1983. The National Institute on Alcohol Abuse and Alcoholism has initiated a grant program for new investigators and the announcement for that program, disseminated in November 1982, emphasizes prevention research. Additionally, a combined Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) program announcement was sent to the field in January 1983 for New Investigator Research Awards in Prevention. This ADAMHA announcement is the first in a series of planned ADAMHA program announcements focusing on prevention research.

The expanding prevention research program supports:

(1) Studies that can provide a basis for development and refinement of prevention strategies especially for high risk groups such as teenagers, young adults and women of child bearing age.

(2) Research which focuses on cultural, familial, peer, occupational, social, and environmental factors which influence or inhibit abusive drinking behaviors, needed as a basis for prevention strategies.

(3) Study of phenomena which include alcohol availability, alcohol beverage sale conditions, economic, legal and judicial parameters, taxation and pricing factors in

relation to consumption patterns and adverse health consequences as they impact on individuals, families and societies.

(4) The role of alcohol in death and injury resulting from home, occupational and recreational accidents; drinking-driving vehicular crashes; crime; suicide and other forms of violence.

(5) Naturally occurring experiments in which legal changes can be assessed for their impact of measurable criteria such as alcohol-related traffic accident morbidity and mortality.

(6) Investigations of ways to reduce and prevent alcohol-related child abuse, neglect and family violence.

(7) Research to measure the effects of alcohol-abuse prevention approaches directed to the general population or at specific high risk groups, such as programs of information, education, early intervention and community awareness and mobilization campaigns, especially those designed to convey alcohol-related health information to teenagers. Projects should focus upon prevention therory development and the testing of strategies aimed at the prevention or reduction of alcohol use particularly for individuals at high risk.

(8) Studies to determine the most effective and cost beneficial ways of preventing alcohol-related problems in a variety of social and environmental contexts.

RESEARCH IN DRUNK DRIVING

Question: What kinds of research in the area of drunk driving do you support? What can research tell us about how to reduce the incidence of drunk driving? What can we learn about the behavior of chronic drunk drivers that will enable us to identify such drivers early and target special attention to their treatment?

Answer: The Institute conducts a wide range of biomedical, behavioral, epidemiologic, prevention and treatment research that can impact on the problem of drunk driving, one of the most costly consequences of alcohol abuse. A number of research projects have been supported to study the impact of changes in legislation on drunk driving fatalities, including the impact of more stringent drunk driving laws, and changes in the minimum legal drinking age. Recent National Institute on Alcohol Abuse and Alcoholism (NIAAA)-supported research found that raising the minimum drinking age decreases the number of drinking and driving accidents. Other research has found that drinking drivers consistently overrate their ability to drive while intoxicated. That this has been scientifically determined can assist the States in educating drunk drivers who have been apprehended.

Increased emphasis is being placed on research related to drunk driving and, under a new agreement signed in March, NIAAA is working collaboratively with the Department of Transportation to

increase research, as well as other activities, aimed at the prevention of drunk driving. A jointly sponsored research workshop on alcohol and the drinking driver is planned to review the state of our knowledge and to identify research needs.

Biomedical and behavioral research can provide a basis for intervention strategies to decrease drunk driving through providing information on the predisposing factors that contribute to drunk driving. Epidemiologic research can provide information about the incidence and prevalence of alcohol-related injuries and deaths, and the relationship of age and other characteristics. We do not know, for example, what percentage of drinking drivers are alcoholics or social drinkers. This a critical factor in developing appropriate intervention. Prevention research is needed to identify high-risk populations and develop more effective educational and prevention approaches. Treatment research is needed to develop improved techniques for rehabilitating the drinking driver.

ADAMHA INTRAMURAL/EXTRAMURAL RESEARCH

Question: Overall, the bulk of your research funds go into extramural versus intramural research. But, even this varies. For instance, in the mental health and alcoholism areas, about 30% of the 1984 funds will go to the intramural program. In drug abuse, however, only 10% is in the intramural program. Do you try to maintain a balance so as not to lose the internal capability?

Answer: We consider it extremely important to maintain an intramural research capacity of the highest quality in each of the three ADAMHA institutes. Our overall intramural plan over the past few years has been to establish intramural programs sufficiently large to address many aspects of the particular disease involved, in both clinical and preclinical settings. Once this basic intramural capacity has been established, major increases are generally requested only when a specific new area needs to be explored, an expensive piece of new machinery would be of significant value to the program, or repairs or renovations are needed.

The reason for the differences you note in the proportion of research dollars spent on intramural programs in each of the three ADAMHA institutes is that the drug abuse program is in a period of transition from its facilities in Lexington to a new one in Baltimore. Construction of a new facility to house the clinical research component has recently been completed, although staffing of that component is still continuing. Thus, its proportion of intramural total research dollars is considerably less at this time than the NIMH program. A number of factors are involved in determining the overall size of each intramural program, including facility size, planned research protocols, availability of bed space, and availability of research subjects. Once fully developed, we attempt to maintain relatively stabilized funding for each intramural program.

MARIJUANA USE BY HIGH SCHOOL SENIORS

Question: Dr. Mayer on page 53 of your justifications it is stated: "In 1979 one out of ten high school seniors used marijuana daily." On page 61 the statement is: "One in fourteen high school seniors reports daily marijuana use." Can you reconcile these statements?

Answer: The statement on page 53 was a summary of drug use in 1979; in the latter reference we were indicating our latest information. For clarity we should have mentioned that the latter was 1981 data. For your information, we have recently compiled the data from our 1982 High School Senior Survey and found that in 1982 one in sixteen high school seniors reports daily marijuana use. Thus there has been a large decrease, from one in ten to one in sixteen, over the 1979 to 1982 period.

EVALUATION ACTIVITIES

Question: What percentage of the National Institute on Drug Abuse's program support budget goes for evaluating the agency's research and training programs? How is this evaluation carried out?

Answer: While NIDA has occasionally used direct operations funds to conduct evaluations, most evaluation projects have been supported with research or training funds. Evaluations are conducted primarily through two mechanisms. Each year one percent of NIDA's total research and training budget is authorized to be available for evaluations of our programs. On average, about half of these funds are actually used for evaluation and the other half are returned for program use. Second, NIDA conducts selected evaluations of its programs directly through contracts. The amount spent on these latter projects varies from year to year, but averages between $300,000 and $400,000.

Examples of evaluations that NIDA has conducted include:

- A review of research on the efficacy of drug abuse prevention programs for adolescents. This evaluation led to the identification of promising areas for further research.

- Evaluation of recent discoveries in the field of pain and analgesia and review of NIDA's involvement in this area of inquiry. This evaluation recommended areas where additional support was likely to yield promising results.

- A technical review on the possible carcinogenic effects of LAAM. The focus was on the relevance and applicability of the carcinogencity of LAAM in rats to clinical experience with this drug. Specific topics under review were: (1) the relevance of the finding of a weak carcinogenic effect of LAAM in laboratory rats vis-a-vis the long term administration of this drug to human subjects, (2) the degree of risk to humans in view of the rat data, and (3) whether NIDA should continue development of LAAM.

TECHNICAL ASSISTANCE AND TECHNOLOGY TRANSFER

Question: What kinds of technical assistance and technology transfer does the National Institute on Drug Abuse provide?

Answer: NIDA provides a variety of technical assistance and technology transfer services related to all aspects of drug abuse. These activities are performed primarily through the Division of Prevention and Communication and involve the following components:

- o The Prevention Branch works closely with State prevention personnel to provide both on- and off-site technical assistance to State and local groups and to quickly disseminate prevention findings.

- o The Technology Transfer branch collects and makes available for dissemination NIDA's research findings. Target audiences include: Federal, State, and local government agencies, criminal justice agencies, parents' groups, public interest and volunteer groups, academia, and business and industry. The branch publishes and disseminates a monthly technology transfer newsletter and provides consultation with various groups as they plan, establish, and manage drug abuse treatment and training programs.

- o The National Clearinghouse for Drug Abuse Information classifies, processes, stores, and retrieves drug abuse information for dissemination to diverse groups with varying information needs. Information is in the form of reports, fact sheets, pamphlets, bibliographies, and other publications.

DATA COLLECTION

Question: What kinds of statistical information on drug abuse incidence and treatment will the National Institute on Drug Abuse collect and compile in FY 1984? Does this represent a reduction in the amount of statistics gathering that has been carried out in recent years? Please provide details.

Answer: NIDA will sponsor the following data collection efforts in FY 1984:

1. The Drug Abuse Warning Network (DAWN). This is an ongoing large-scale voluntary data system which collects, processes, and analyzes drug-related episodes from approximately 900 hospital emergency rooms and medical examiners across the United States. DAWN, which annually collects data on over 120,000 episodes involving the mortality and morbidity of drugs in our society, provides important intelligence on the dynamics of drug behavior, is useful for epidemiologic outbreak analysis, and permits rapid assessment of trends.

2. The National Drug and Alcoholism Treatment Utilization Survey (NDATUS). NDATUS is a survey of the scope and use of drug abuse and alcoholism treatment and prevention resources throughout the United States and its territories. In FY 1984 NDATUS is proposed as a joint effort with the National Institute on Alcohol Abuse and Alcoholism (NIAAA), and the States. In 1984 this biennial voluntary effort will be modified to more closely reflect the capabilities and needs of the States and will be used by Federal and State agencies to ascertain the kinds of treatment available, numbers and demographics of clients treated, and fluctuations in funding allocations for those services.

3. The High School Senior Survey. This annual, cross-sectional survey is directed at the drug abuse and related attitudes of high school seniors in the United States. The FY 1984 survey will be the eighth consecutive year of this survey.

4. NIDA is attempting to collect critical client-specific data on a voluntary basis from the States. The Omnibus Reconciliation Act of 1981 rescinded responsibility for the mandatory collection of these data in favor of the direct Block Grant allocation to States. These data are critical for assessing consumption and use pattern changes in illicit drugs such as heroin and cocaine. These are also vital to national projections and comparisons between and among States and localities.

Smaller studies are also conducted, primarily with the focus limited to subpopulations, and are funded through the project grant mechanism. In addition, NIDA conducts a National Household Survey which provides information on drug use from a representative sample of our Nation's households. This survey will not be funded again until 1985, representing a 3-year interval between national surveys.

While there has been some reduction in NIDA's statistical data-gathering efforts through the loss of required treatment data reporting and increased time intervals between survey points, NIDA continues to examine alternate means and improvements in methodologies to assure the reasonable availability of essential national drug abuse information.

USE OF CONSULTANTS

Question: What use does the National Institute on Drug Abuse (NIDA) make of consultants in its operation? What kinds of functions and studies do they perform for you? What percentage of your NIDA budget goes for consultant services?

Answer: NIDA's consultants perform several functions for the Institute. First, they make up the National Advisory Council on Drug Abuse. Council members are appointed by the Secretary of the Department of Health and Human Services to review grant applications, and make final recommendations to the Director of the Institute on which projects they believe merit consideration for funding. In doing so, the value of a proposal is reviewed against stated national research priorities in the drug abuse

field. This group also serves in an advisory capacity to the Institute Director, on specific issues of drug abuse as well as overall policy, to which they believe the Institute should address itself.

Consultants are also appointed, on an ad hoc basis, to serve on contract review committees. Their purpose is to evaluate and rate contract proposals being considered for competitive award.

Finally, NIDA uses the expertise of professional consultants to write, edit, and review scientific papers in the drug abuse field, to provide technical assistance to NIDA's professional staff in areas related to drug abuse, and to conduct or participate in seminars.

Slightly over one percent of NIDA's budget is for support of consultants.

NATIONAL CLEARINGHOUSE FOR DRUG INFORMATION

Question: What is that status of the National Clearinghouse on Drug Abuse Information? Do you plan to keep it in operation or will it be closed as was the Mental Health Clearinghouse?

Answer: The National Clearinghouse for Drug Abuse Information (NCDAI) is an ongoing function of the Institute. It is a critical component of NIDA's research and prevention dissemination efforts. A recent DHHS panel evaluated the effectiveness of selected clearinghouses within the Department and concluded that the NCDAI provided a needed and cost-effective service. We estimate that the Clearinghouse will distribute approximately 2.5 million publications in FY 1983. NIDA definitely intends to continue to operate the Clearinghouse.

CHRONIC MENTAL PATIENTS IN JAILS

Question: As a result of the deinstitutionalization movement, it would appear that an increasing number of chronic mental patients have become the responsibility of our Nation's jails and prison authorities. The Committee was pleased, therefore, to recently learn that the NIMH has been addressing this matter and has even published a mongraph entitled, "Mental Health Services in Local Jails".

The Committee would appreciate learning -- given the severe problems in our jails and prisons which were highlighted in this report --what plans are being proposed for further research in this area?

Answer: NIMH currently has two active research projects, one approved project awaiting funding, and one initially approved project still in the peer review process that address important issues about the mentally ill in jails and prisons. One active project - Interfacing Local Jails with the Mental Health System - involves unique community followup research on 32 local jails and mental health systems that participated in an earlier Federally sponsored training program that had been developed as a direct result of the work described in the NIMH monograph. This followup

research has found that jail mental health programs may assume many different organizational forms in response to specific local needs (i.e., there is no one "best" way), have a tendency toward rapid turnover of staff, and are perceived by staff to have a calming effect on institution tensions.

The other active project, and the approved project awaiting funding, concern the application of new NIMH-developed diagnostic tools to estimate the prevalence of mental disorders in a state prison system and a large urban jail respectively. The active project - Epidemiological Study of Prisoner Mental Health - is ascertaining the prevalence of mental disorders in inmates in North Carolina prisons. The other project will ascertain the prevalence of mental disorders in pretrial inmates admitted to the Cook County, Illinois jail. This new research on prevalence will bring much needed scientific rigor to otherwise imprecise and unreliable instruments as well as demonstrate the practical utility of the new NIMH-developed Diagnostic Interview Schedule in correctional settings.

Finally, a project that has initially been recommended for approval but is still in the peer review process will examine the incidence and institutional histories of a particularly difficult-to-manage inmate, i.e., the offender who is both disruptive and mentally disordered. Such disturbed disruptive inmates consume a disproportionate share of custodial, treatment, and management attention and resources in prisons.

In sum, NIMH is addressing the issues concerning mentally disordered inmates of jails and prisons by providing necessary diagnostic tools and baseline epidemiologic information, by continuing to develop and assess jail mental health program models, and by identifying the characteristics of a particularly difficult-to-manage mentally ill inmate, the disturbed disruptive inmate.

REDUCTION OF POSITIONS

Question: The budget for direct operations assumes a reduction of 22 positions and $538,000. How can you absorb these reductions given the increases proposed in the grant program?

Answer: The budget does not reflect any reduction in positions, but does reflect elimination of 22 full-time equivalents (FTE's) relating to other-than-permanent positions. These FTE's will be saved through increased management efficiency and reduced overhead costs, and will not affect staff allocated to research grant activities.

GRANT ADMINISTRATION

Question: What is the average cost of administration per grant?

Answer: The direct operations budget of the institute is not developed in such a way as to provide a defensible answer to this type of question without a complete and consistent understanding of what is involved in the administration of a grant. NIMH awards project grants, contracts, cooperative agreements, purchase orders, small grants, and center grants to

name the most numerous. All these awards are received, processed, reviewed and monitored by a variety of personnel best skilled in the particular aspects of the program, the process, and the mechanism involved. These same people are also often involved in non-award activities such as dissemination of information, provision of technical expertise, and program policy input and it is extremely difficult to separate their time and the cost to the agency between grant administration and other activities. Therefore, while the question is certainly a reasonable one, it cannot be responsibly answered without careful definitions and a more involved review than allowed here.

CONSULTANTS

Question: What use does the National Institute of Mental Health make of consultants in its operations? What percentage of your total operating budget goes to private consultants? What functions do they perform that could not be performed by your own employees?

Answer: Approximately $300,000, or 0.1 percent of the total NIMH budget, or 0.9 percent of its direct operating budget, will be used for private consultants. The Institute uses private consultants for three general purposes. First, they assist, advise, or render opinions on research techniques or bodies of knowledge requiring expertise, or a level of expertise, not available to it through its staff. Secondly, they are used as members of advisory committees, such as the National Advisory Mental Health Council, which are prescribed by law. Finally, they are used in collaboration with the Health Care Financing Administration to assist in assessing the quality of care provided to mentally ill patients who reside in mental hospitals which participate in the Medicare and Medicaid programs.

PROGRAM EVALUATION

Question: What percentage of the National Institute of Mental Health research and training budget is spent on the evaluation of the programs you support? How do you go about evaluating the research you fund?

Answer: Approximately one percent of the research budget is spent for evaluation. In recent years, no training funds have been spent for this purpose, as most of the training appropriations have reflected Congressional restorations for specifically mandated purposes.

The National Institute of Mental Health continually evaluates the research it funds through a variety of formal and informal mechanisms including peer review, self-review and evaluation against predetermined objective criteria. Examples of these processes are:

1. Initial reviews of each individual grant through the peer-review process by Initial Review Groups and the National Advisory Mental Health Council for an assessment of the quality, importance, and policy implications of projects on a grant-by-grant basis.

2. Periodic reviews of specific grant portfolios as they relate to state-of-the-science and the scientific opportunities of the field.

3. Targeted assessments of particular initiatives to determine the extent to which they are meeting predetermined goals.

4. Informal and formal staff evaluations and reviews associated with preparing annual reports, budgets, etc., including an annual review of each program by the Office of the Director.

5. Assessments of productivity of the research and its training components.

NATIONAL CLEARINGHOUSE

Question: What is the status of the National Clearinghouse on Mental Health information? Has the Clearinghouse terminated its operation? If so, why?

Answer: The computerized data base of the National Clearinghouse for Mental Health Information (NCMHI) is no longer updated. In 1982 a New York firm, Plenum Publishing Corp., announced its intention to provide an abstracting and indexing service to libraries and other institutions. Since the service is already being provided by private industry, the National Institute of Mental Health (NIMH) determined that it would no longer update the computer data base. However, the other two sections of the NCMHI, the Mental Health Library and the Public Inquiries Section, are still functioning and providing service to the public.

Question: Where will mental health professionals and the public go for the types of mental health information and data searches provided by the National Clearinghouse on Mental Health Information?

Answer: Not only will professionals and the general public be able to use the new service provided by Plenum Publishing Corp., but they will also continue to use the services provided by the American Psychological Association and the National Library of Medicine. Publications of the NIMH will continue to be available through its Public Inquiries Section. Interlibrary loan service continues through the Mental Health Library.

RESEARCH TRAINING

Question: In what areas of mental health research training are there shortages?

Answer: The most urgent need is to train more individuals to do clinical research. For the most part, this would mean providing training to individuals who are already skilled clinicians, so that they can do research on the causes and treatment of mental illness. Other high priorities include (a) training in the biological, pharmacological, and biobehavioral areas for work on brain chemicals and the use of new technologies such as the PET scanner to study the brain of normal and disturbed individuals; (b) training for

prevention research; and (c) training in clinical epidemiology, mental health economics, and services sytems research.

In addition, our overall goal is to maintain a constant supply of biological, behavioral, and clinical researchers prepared to conduct research on a wide range of mental health problems.

Question: What percentage of applications for research training assistance will you be able to fund in FY 1983 and FY 1984? How do you decide which applications are funded and which are not?

Answer: In FY 1983 we will be able to fund 26 percent of the applications received for research training grants. We expect to be able to fund fewer than 10 percent in FY 1984. It should be noted that not all applications received were approved for funding by the National Advisory Mental Health Council.

All applications undergo a dual review process. First an Initial Review Group (IRG) composed principally of non-governmental experts in the application's program area reviews each submission; recommends it either for approval or disapproval; and, if the former, assigns a priority score which reflects the judged merit of the application. The National Advisory Mental Health Council reviews the work of the various IRG's and indicates its agreement or disagreement. All applications which have been approved by both these groups are sent to the program units for consideration for funding. Final funding decisions are recommended by program staff and approved by the Institute Director. Grants are funded until the available money is exhausted. In general, those applications with the best IRG priority scores are funded first, although small adjustments may be made for grants in areas of high program priority. In FY 1983 90% of the new and competing research training grants which were funded had priority scores of 140 or better, on a scale of 100 to 500. The range of priority scores on funded projects was 108 to 160.

Question: What other sources of funding for mental health research training, if any, exist outside the Federal government?

Answer: While the government provides most of the funds for research training, funds may also be obtained from the universities themselves, regular research and research Center grants, teaching and research assistantships, and loans.

STUDIES LEADING TO CORPORATION PROPOSAL

Question: It. is our understanding that the General Accounting Office, at the request of the House Authorizing Committee, is conducting a thorough review of the operations of Saint Elizabeths and the appropriate Federal and city role and responsibilities. What studies were conducted by the Administration prior to developing its position that a corporate structure is appropriate?

Answer: It is our understanding that the House authorizing Committee has asked the General Accounting Office to review the various steps necessary to transfer St. Elizabeths directly to the District of Columbia government. Three years ago a corporation form of governance was first studied and formally proposed by a joint task force appointed by the District of Columbia Mayor and the Secretary of the Department of Health and Human Services. Since that time, extensive reviews of the initial proposal have been undertaken by DHHS and OMB.

For the past eighteen years efforts have been consistently made to remove St. Elizabeths from DHHS and unify it with local mental health system. The reasons for this restructuring are several: we believe it inappropriate for the Department to administer what has become essentially a state psychiatric institution performing direct service delivery for local population; to the extent that mental health services to District of Columbia residents are administered by two governments, duplication, fragmentation and conflict have resulted; and although SEH provides virtually all local public inpatient mental health service and a majority of outpatient services, the District of Columbia has never had any voice in or control over SEH operations or the services it delivers.

The corporate form of governance is believed to be the most appropriate because the District of Columbia's Mayor has stated on several occasions that direct transfer of Saint Elizabeths is not appropriate. The concept of separating direct health service delivery from the local government served has proven effective in several other localities, including establishing a corporation to operate D.C. General Hospital instead of the District's Department of Human Services.

CONSULTATION WITH DISTRICT OF COLUMBIA

Question: What consultations were held with the city Government?

Answer: Consultations over a four year period have involved all operational levels in the Department, Office of Management and Budget and the District - including the Director of the OMB, the Secretary of Health and Human Services, and the Mayor of the District of Columbia.

TRAINEES AND EMPLOYEE PATIENTS

Question: St. Elizabeths hires employee patients and also has budgeted for trainees in FY 1984. What is the total number of trainees and employee patients budgeted for 1984?

Answer: The total budgeted level for employed patients and trainees would be 1[illegible]2, which is the same as in the current year.

Question: Has OMB required you to count these individuals against your overall ceilings?

Answer: We have been advised by OMB that interns, residents, and patient workers must now be charged against the hospital's full time equivalent ceiling. Previously, these individuals were considered ceiling exempt.

Question: Given the fact that the budget assumes position reductions based on the remote possibility that legislation will be enacted on August 1, do you believe that these trainees and employee patients should also count against your limit?

Answer: If the hospital becomes a corporation on August 1, 1984, the manner of counting trainees and patient employees will not pose a problem. No other Federal agency considers patient workers as ceiling-exempt.

SUPPORTABLE EMPLOYMENT

Question: Is it correct that you have adequate funds to support 3,650 full-time positions but would need an adjustment in your personnel ceiling in the event the corporation legislation is not enacted?

Answer: Should the corporation proposal not be inacted, the SEH full time equivalent ceiling will need to be reevaluated in the context of management reviews that are planned as well as total DHHS resources.

EFFECTS OF ANTIPSYCHOTIC DRUGS

Question: I understand that there is some serious concern over the side effects caused by continuous use of antipsychotic drugs. What is being done to research these problems and to develop new, more effective drugs?

Answer: The most serious concern over side effects caused by continuous use of antipsychotic drugs centers on concern over tardive dyskinesia (TD) which occurs in about 20% of patients on maintenance phenothiazines.

In recent years, NIMH has focused its efforts on research into such long term side effects by: (1) using low doses of antipsychotic medications to prevent relapse, hence reducing the risk for TD; and (2) using antipsychotic medications only at time of relapse. Preliminary results indicate that both treatment strategies lessen the risk for TD. NIMH also has ongoing research programs seeking drugs to treat TD when it develops and research for

new drugs to treat psychosis without the risk of TD. One such new drug is CCK, a gastrointestinal peptide, which in preliminary studies shows promise as an antipsychotic, but poses no risk for TD.

Additionally, the Institute is increasing support in the area of behavioral toxicology, a way of predicting adverse effects of drugs in chemical and animal models.

CAUSES OF SEVERE MENTAL ILLNESSES

Question: Is there evidence that severe mental illness as well as alcoholism are traceable to biochemical and genetic causes? Has this been reflected in NIMH's research efforts?

Answer: It has long been known that close relatives of schizophrenic patients are more likely to develop schizophrenia than persons who are not. The children of one schizophrenic parent, for example, have a 10% chance of developing schizophrenia; if both parents have schizophrenia, the risk is estimated to be considerably higher - around 40%. By comparison, the risk of schizophrenia in the general population is 1 to 2 per cent. The problem in interpreting these findings has been that it is difficult to separate the genetic contribution from the disruptive influence of the illness and multiple parental hospitalizations on the development of schizophrenia in the child.

Two types of increasingly sophisticated studies have combined to provide stronger evidence on the importance of genetic factors in at least some types of schizophenia--twin studies and the studies of adopted-away offspring of schizophrenia parent(s). The former have shown that identical twins, as compared to fraternal twins, show a higher rate of concordance for schizophrenia (reported rates range from 35-38% for identical twins and 9-26% for fraternal twins). This finding that having identical genetic composition increases the concordance rate for schizophrenia provides additional support for the genetic contribution to schizophrenia, but the effects of the rearing environment cannot be separated out. The third strategy--adoption studies--have been aimed at separating of the effects of environment and heredity. Findings from these studies indicate that being biologically related to a schizophrenic increases the risk for schizophrenia, even when the related individuals have no personal contact.

On the basis of the family, twin, and adoption studies it appears that schizophrenia has an hereditary basis. The exact nature of the genetic influence is unknown at the present, but most scientists would place it in the category of a genetic predisposition. The NIMH is currently supporting studies which attempt to extend these findings into new populations and to determine more exactly the mode of inheritance and which aspects of schizophrenia are genetically mediated.

It is also important to note in this regard, however, that as impressive as these findings may be, they do not tell the complete story. For example, although having a schizophrenic parent increases the risk for schizophrenia to 10 percent, it is important to understand that 90 percent of children of a schizophrenic parent do not develop schizophrenia and in addition, 90 percent of the

total population of people affected by schizophrenia do not have a first degree relative with the disorder. It becomes, therefore imperative that conditions which protect a person from developing schizophrenia or which affect individuals without a genetic predisposition also be included in a balanced research program.

Another set of severe mental disorders are the affective disorders. These disorders are a collection of disorders characterized by abnormalities in emotion, thinking processes, basic human drives (such as hunger, sleep, and sex), attention, and motor function. Genetic factors have been demonstrated in the etiology of depression, using a variety of approaches including studies, biological markers, pedigree analyses, and family studies. Biological dysfunctions during depression are numerous, and involve the chemical neurotransmitters, neuroendocrine function, and enzymes.

Data from population genetic studies have consistently found that the rate of unipolar depression in the relative of unipolar depressives is twice that in the relatives of matched non-depressed subjects. The rate jumps to 4:1 when comparing the relatives of bipolar patients with the relatives of matched non-depressed subjects. Twin studies have found that the concordance rate of bipolar illness is four times higher for monozygotic twins as for dizygotic twins, and for unipolar depression the ratio is 2:1.

Another strategy is to compare the prevalence of the disorder in the biologic and adopted parents of patients who have been adopted. This approach can provide a powerful test of the genetic verus environmental influences on the development of the disorder. A recent study by Mendlewicz found the prevalence of affective disorders in the biological parents of bipolar adoptees to be four times greater than that of affective disorders in the adoptive parents, lending support to the genetic hypothesis.

Other approaches to the genetics of affective disorder have produced several promising leads for specific chromosomal locations for the inheritance of affective disorders. In addition to genetic factors, biochemical and other biological factors have been implicated in the etiology of several mental disorders.

It is clear that alcoholism has genetic correlates and thereby of necessity predisposing biochemical correlates as well. At the genetic level, studies of alcoholism inheritability have shown that the children of alcoholics are, as a whole, four times more likely to develop alcoholism than children without an alcoholic biological parent. These studies have been well controlled to separate and distinguish the families' environmental influence from biologically transmitted factors. More recent genetic studies have demonstrated two unique forms of inherited alcoholism. A milder form, affecting both males and females, occurs three times more often among children of alcoholics then non-alcoholics. The milder form requires environmental provocation in addition to heredity for expression. The more severe form, found to date only among males, is expressed independent of the environment, and increases risk nine fold.

When a trait is demonstrated to be inherited, it establishes that a specific gene, responsible for some element of the trait or disease, or increasing the risk for disease, must be expressed in susceptible individuals. All genes are biochemically expressed (that is their eventual products are proteins). Thus, the demonstration of a genetic link establishes that biochemical factors are involved in the expression of the condition, or risk for it. Work is now proceeding with animal models to identify the specific biochemical factors which place susceptible individuals at risk for alcoholism.

NURSES ON ADVISORY COMMITTEES

Question: Last year this Committee instructed your agency to insure an increase in nurse participation on advisory comittees. In you budget justification, you have responded by indicating sympathy with the Committee's interest but, have provided the caveat: "Nonetheless, there is only a small pool of nurses who have appropriate scientific training, experience and accomplishments to meet our needs for specific types of research expertise on these committees." Since the Committee directive was not limited to research committees, the question is raised: Are all of the Institute's committees soley research-related?

Answer: All of ADAMHA's 26 committees deal primarily, if not exclusively, with research and research training issues. We have 16 initial review groups, all of which provide scientific merit review of research or research training proposals. The three Boards of Scientific Counselors provide expert advice on the quality and direction of intramural research programs. Each of the three National Advisory Councils provides policy advice on the entire range of an Institute's programs and activities. Since the vast majority of each Institute's funds are for research, most of the policy advice of Councils deals with research issues. Also, Councils provide secondary review of research and research training grant applications. The Rape Prevention and Control Advisory Committee advises us on the entire range of policies and activities of the NIMH's rape center, most of which relates to programs in this area or dissemination of research information.

Question: Even if the committees are research related, is it not beneficial to have representatives of professionals other than scientists to provide support?

Answer: It is essential to have only experts in the field on our Initial Review Groups, since by law (sec. 475 of the PHS Act) we are required to provide peer review of research and research training grant applications by eminently qualified individuals. This legislative requirement stems from a long history of success in the health area in using the mechanism of review by peers to select those applications showing evidence of highest quality. It is equally essential to have only eminent scientist on our Boards of Scientific Counselors, since their advice relates to scientific productivity and potential of individual investigators and research laboratories.

For our policy advisory committees (Councils and Rape Committee), a critical mass of highly respected scientists is

essential. While the legislative authorities and functions of these committees do permit the participation of a wide range of professionals and other leaders in the field, we must include representation from a wide variety of disciplines and professional organizations, the biomedical and applied social sciences, public affairs leaders, and of course, scientists familiar with the ADAMHA research programs.

Question: It is our understanding that you issued a directive to each of the Instiutes on April 5th to expand their search for more nurses to serve on committees. How many advisory committees does NIMH have?

Answer: NIMH currently has 11 advisory committees.

Question: How many nurses have been appointed recently?

Answer: One nurse was appointed last year, and another is about to be appointed. Two others currently serve on other advisory committees.

Question: Finally, why did you wait until April 5 to issue the directive?

Answer: I believe this question refers to my memoranda of April 5 to the Institute Directors urging increased efforts to identify and appoint nurses to advisory committees. Since 1981, the Office of the Administrator has raised this issue several times with Institute Directors and their staff. There has been concerted effort to identify nurse candidates for our committees, and my recent memoranda were intended to serve as a reminder of the need to continue and, where appropriate, expand our attention in this area.

RESEARCH TRAINING

Question: Your budget for research training proposes an increase of less than $400,000 (from $17,337,000 in FY 1983 to $17,702,000 in 1984). The justification indicates that this is sufficient to maintain the number of trainees at 1,000. In the mental health area you indicate a shortage of physician researchers. On what information is this based?

Answer: Major guidance for the research training programs of NIH and ADAMHA is provided by the Committee on a Study of National Needs for Biomedical and Behavioral Research Personnel, Commission on Human Resources, National Research Council. The Committee has consistently reported over the years that the most severe shortages of biomedical and behavioral research personnel exist in the clinical sciences fields, and has urged a greater emphasis specifically on training physicians in this area. Concurrently, NIMH has placed its major research training priority on the development of more clinical researchers, particularly those who will be able to conduct research utilizing techniques and findings in biomedical research. This area is the most rapidly growing and promising one in mental health research. Lastly, a panel of leading clinical researchers which recently convened at

NIMH stated that the greatest need in their field was increased training of psychiatric clinical researchers. Because of the greater ease of training for clinical careers, and the greater financial rewards of clinical work, special emphasis is needed in order to train more physician researchers.

Question: Since you have also indicated a shortage of nurse researchers competent to serve on your advisory committees -- shouldn't you be increasing training for these professionals?

Answer: The NIMH does not direct its programs toward research training for any discipline per se, but rather provides support for research training in certain areas. These include the basic biomedical and behavioral sciences, and preparation for work in mental health epidemiology, clinical research, clinical services and service systems research, and prevention research. The training of minority researchers is also supported. Nursing programs are eligible to apply for support for training in any of the areas listed above. Few have applied in the past, principally because few nursing training programs are specifically oriented to preparation for careers in research. NIMH staff would be pleased to provide technical assistance to any nursing program which wished to develop a research training application.

Question: Provide the Committee with a breakdown of training grants per professional group.

Answer: The breakdown for the ADAMHA research training program is provided in the following table. The numbers have been amended slightly from the figures in the budget justification due to the elimination of earlier proposed stipend increases.

Area	Grants	Fellowships
Psychiatrists	7	4
Psychologists	47	52
Nurses	1	---
Social Workers	1	---
Social/Behavioral Sciences	33	23
Epidemiology	8	4
Biological Sciences/ Neurosciences	27	49
Pharmacology	4	8
Other	3	22
	131	162

CLINICAL TRAINING

Question: The budget proposes to terminate all Federal support for clinical training in the mental health professions--a cut of $20.1 million. Is it your contention that the program has accomplished its aims and that there are no shortages?

Answer: No, I would not say that there are no shortages. The clinical training programs of the National Institute of Mental Health have been successful in greatly increasing the supply of mental health professionals in all disciplines, and in improving the

quality of their training and orienting it more closely to national needs. In addition, NIMH support has helped many States identify and deal with their manpower development problems and has assisted in the training and recognition of paraprofessionals/mental health workers.

Shortages still exist, particularly in regard to geriatric and child mental health specialists, psychiatric nurses, and minority mental health professionals. The Administration believes that training programs should now be strong enough to continue without Federal support, and that students who plan on professional careers should, if necessary, incur loans to pay for their education.

Question: On what evidence do you base this conclusion?

Answer: The evidence for the success of the program lies in the substantial increase in the number of mental health professionals. Between 1950 and 1982 the number of psychiatrists has risen from 7,000 to 31,000; health service providers in psychology from less than 5,000 to 33,000; masters level psychiatric nurses from almost none to over 7,000; and trained mental health social workers from under 5,000 to over 30,000.

Question: Have you done some out year studies on the effects of eliminating those programs?

Answer: No. We have not conducted any formal studies on the effects of the elimination of support for clinical training.

Question: The budget indicates there are 31,000 psychiatrists and 7,000 psychiatric nurses. From a layman's viewpoint, it would appear to me that the ratio of doctors to nurses (4-1) is rather unbalanced in this field. I'd like your comment on this observation.

Answer: While there are approximately 7,000 employed psychiatric nurses trained at the masters level, the total number of employed psychiatric nurses (R.N.) at all levels of training was almost 53,000 in 1977-1978 and is estimated to exceed 55,000 today. Thus the ratio to which you refer is much more in line with that of non-psychiatric health staffing needs.

ADAMHA BLOCK GRANT

Question: What is the rationale for transferring the administration of the Alcohol, Drug Abuse and Mental Health Block Grant from ADAMHA to the Office of the Assistant Secretary for Health?

Answer: The proposal to transfer the ADAMHA block grant is one which encompasses all the health block grants. It is our position that the grants and financial management aspects of administering these programs can be done most efficiently in a centralized location, requiring fewer staff and overhead costs. Under the Administration's New Federalism legislative proposal, these health block grants would be consolidated within one "megablock" grant to each State, and this program would be

administered from a centralized location rather than at the agency level. Our 1984 budget thus represents a preliminary step towards centralizing the administrative and program responsibilities of former categorical programs in line with the New Federalism initiative.

Question: What oversight activities does the Federal government maintain over the States' operation of the ADAMHA Block Grant to assure that program goals are being met?

Answer: The Federal government performs all oversight activities required by the block grant legislation. These include receiving from the States assurances that they will comply with program provisions of the block grant; ensuring that States audit their programs annually and reviewing this audit; reviewing the annual State reports on block grant program activities; and conducting compliance reviews in several States each year. Compliance reviews were held in five States in 1982, and ten other States will be reviewed in detail in 1983.

Question: If States request technical assistance in their operation of the block grant, who would provide it, the Office of the Assistant Secretary or the Alcohol, Drug Abuse and Mental Health Administration?

Answer: Programmatic assistance will continue to be provided by the Alcohol, Drug Abuse and Mental Health Administration, as we have the professional and program expertise to do so.

HEROIN RESEARCH

Question: Your budget states that of the 28,000,000 Americans abusing illegal drugs, only 450,000 - 500,000 use heroin. Yet, of the $50.6 million requested for research, $8.1 million is for heroin.

Can you tell us why this is seen as your most important research effort?

Answer: NIDA places a high priority on research in this area for two reasons. First, the harmful effects resulting from heroin use are far out of proportion to the number of people using it. Accidental deaths from heroin are greater than all other illegal drugs combined. Heroin users also suffer a disproportionally greater number of diseases than other drug users. This burden is further compounded by the degree to which heroin users turn to crime to support their addictions. We have clearly documented that heavy heroin users commit an average of at least two crimes every three days, and these are crimes other than the possession or sale of drugs. This means that a typical heroin addict commits about 247 crimes a year. Less than one percent of these crimes ever result in a conviction. The cost of such crime has been conservatively estimated at $16 billion a year in stolen goods. Treatment of heroin users significantly reduces their criminal behavior and often restores addicts to productive lives. Clearly, research which is likely to result in the development of

additional improved detoxification and treatment agents, such as naltrexone and buprenorphine, has enormous health and financial implications.

Second, research on heroin and other opiate compounds provides a sound approach to the study of the neurobiology and neurochemistry not only of addiction, but also of other biological processes of fundamental importance. Over the last several years NIDA sponsored research was responsible for the identification and isolation of opiate receptors within the central nervous system and the subsequent discovery of endogenous opiate-like substances. This research has sparked vigorous work not only in the area of drug abuse but also in the fields of neurological disease, mental health, cardiac and pulmonary function, and pain and analgesia. Within the past two years this research has focused on the molecular and cellular mechanisms involved in opiate action. Of primary interest is the identification of distinct types of opiate receptors and the identification of various pathways by which the naturally occuring opiate-like substances are synthesized and inactivated in the brain.

NIDA supported researchers have been the world leaders in these scientific breakthroughs. We are confident that continued research will lead to a thorough understanding of the addictive properties of opiates including how they produce euphoria and control pain. This work will make possible entirely new methods of preventing and treating drug abuse. Already we are beginning to see the appearance of new pharmacotherapies for the treatment of narcotic addiction which are based on fundamental studies of opiate receptors and endogenous opiate-like substances.

DRUG ABUSE PREVENTION AND TREATMENT RESEARCH

Question: How much of the $71.7 million NIDA budget will actually be devoted to drug treatment research versus prevention activities?

Answer: About $5.8 million is specifically earmarked in our FY 84 budget for prevention research and about the same amount will be spent for treatment research.

I should point out that, although it is useful and necessary to indicate that some research projects are specifically directed at increasing our knowledge concerning prevention and improving our ability to treat the victims of drug abuse, much of the research which, in our budget documents and elsewhere, is characterized for other purposes provides vital contributions to these objectives.

EFFECTIVENESS OF PREVENTION PROGRAMS

Question: We know that the anti-smoking campaign has had a positive effect, reducing the number of smokers but, from your budget indicating 28,000,000 Americans abuse drugs and 30% of

those aged 18-25 have used cocaine, -- I wonder about the effectiveness of our drug prevention programs. Are we making any headway in this effort?

Answer: Yes, we are making headway. It can be measured in two ways. First, while large numbers of Americans are using drugs, our surveys have shown a decline in the numbers of people using marijuana and cocaine, particularly among young people. While we cannot be certain that this decline is the result of our prevention programs alone, some evidence of their success is indicated by the increase in the number of people who report an increase in their assessments of the risk associated with drug use. A decrease in peer acceptance of drug use has also been reported. These are the two attitudes our prevention programs have been most concerned with fostering. Second, while the drug abuse prevention field is a relatively new one, recent evidence has demonstrated the effectiveness of at least certain prevention programs in specific situations. Further research is now underway to evaluate these prevention programs when applied in different situations and to larger groups. Research in this area is one of the Institute's highest priorties.

Question: What have you found works best?

Answer: The most promising prevention programs are those which are based on the "saying no" strategy initially developed in the smoking prevention field. This approach focuses on factors which motivate young people to start using tobacco, and the peer pressure that encourages students to smoke. It also trains students to resist the subtle and explicit pressures from peers or the media to smoke. This prevention technology of "positive peer pressure techniques" has been found to be effective in reducing the rate of onset in tobacco smoking and recent studies we have made suggest its effectiveness in reducing alcohol and marijuana use as well. We are currently supporting research to explore more fully the use of this strategy in drug abuse prevention.

ST. ELIZABETHS FUNDING SHORTFALL

Question: The appropriation request of $62.7 million for St. Elizabeth's Hospital assumes a District of Columbia reimbursement of $54.5 million. However, it has come to our attention that the request submitted by OMB on behalf of the D.C. Government is only $29.5 million -- leaving a potential $25 million shortfall in funds requested for operation of the Hospital. Do you have any indications that an amendment will be submitted to revise the D.C. budget?

Answer: We are not aware of any plans to submit an amendment on behalf of the District of Columbia at this time.

CURE FOR SERIOUS MENTAL ILLNESS

Question: Is there any hope that NIMH can help find a cure for serious mental illnesses - the schizophrenias and the affective disorders? How long will it take? Is it a matter of money? What about the availability of research scientists? Should more training

opportunities (Federal money) be made available? How can more basic scientists be involved in these efforts?

Answer: There is certainly hope that NIMH supported scientists can help find a cure for schizophrenia and the affective disorders that afflict nearly one-fifth of the population of this country. For affective disorders, if by "cure" is meant an effective treatment for an episode of illness and prevention of future episodes, the mental health field has made considerable progress. Currently available treatments such as the antidepressant drugs, lithium, and neuroleptic agents are effective in a majority of individuals with affective illnesses. However, not all persons afflicted with affective disorders respond satisfactorily to available treatments. Thus, more progress has to be made. There are still many unresolved questions and problems. Pharmacological understanding of the mode of action of antidepressant and antimanic drugs is still incomplete.

NIMH scientists believe that the recent advances in technologies for diagnosis and classification, brain function imaging, brain receptor assays and development of new psychoactive agents should assure continued progress over the next decade for both treating the affective disorders and for understanding their etiological bases so that there can be primary prevention or a "cure".

For schizophrenia, however, we still do not have sufficient understanding of the nature of this disorder to state with any degree of certainty when a cure will be found and exactly how much money will be required to do the job. What is needed is to increase the small cadre of research scientists directly interested in and studying both the etiology and the treatment of the disorder.

Few researchers are currently attracted to work in this area possibly because of the difficulty in relating to these patients who are often withdrawn and caught with their delusions and hallucinations. The chronic and recurring nature of the disorder also has a dampening effect for young scientists. Sufficient financial support to keep a group of investigators active in order to form a "critical mass" of activity and to provide for the training of new investigators is essential.

Obviously, the availability of money and research scientists is a factor since these resources control the amount of new research and new approaches that can be explored. Both basic and applied research scientists are required to develop and evaluate promising approaches. The training of these individuals should be of high priority.

DIAGNOSTIC AND TREATMENT PROCEDURES

Question: It is apparent that mental health providers do not have necessary diagnostic and treatment approaches to help the severely mentally ill and their families, and at times their efforts may even be counterproductive. What is your thinking about the present "state of the art"? What can be done about this?

Answer: The Institute recognizes the need for accurate and valid diagnosis and rational and effective treatment. Psychiatric diagnosis has come a long way in accomplishing impressive reliability. This has been accomplished through careful selection of diagnostic criteria and the development of comprehensive structured interviews, and the training of diagnosticians in the use of recently developed instruments in this area. A considerable amount of research is now devoted to the establishment of the validity of various diagnostic categories and the achievement of greater refinement in differentiating some of the more difficult cases. These efforts include: the development of behavioral and biological markers and independent laboratory assessments. Moreover, several genetic and longitudinal-followup studies of psychiatric probands and their first degree relatives are in progress to help ascertain similarities and differences between different types of affective disorders and types of schizophrenias.

The Institute has special programs on the psychopharmacological, somatic and psychosocial treatments. These programs are attempting to develop new and more effective specific treatments for the severe mental disorders. Data on the effective use of both pharmacological and psychosocial treatments in the affective disorders, schizophrenia, and anxiety disorders have been accumulating for about three decades in research settings. However, the need for training mental health providers in the most recent and sophisticated diagnostic procedures and the application of research findings regarding the psychopharmacological and psychosocial treatment of various mental disorders is an absolute necessity in order to upgrade and improve the quality of care.

MENTAL ILLNESSES OF CHILDREN

Question: Families have been blamed in the past for causing their childrens' serious mental illnesses. Is this attitude still pervasive among professionals? What do research findings indicate on the causes of the serious mental illnesses?

Answer: Families are no longer regarded as accountable for serious mental illnesses in the way they were in the past. Etiology (causation) of mental illness is now thought to be an interaction between biological, environmental, and experiential factors. Evidence suggests that there are predisposing biological (genetic) factors in some types of serious depression and schizophrenia. Yet, since most children seen as biologically predisposed do not develop these or other disorders, there may be an environmental contribution that facilitates or impedes the development of these illnesses; thus our current concern is with both vulnerability and protective factors in mental illness.

Current research on serious childhood mental illnesses examines an array of biological, environmental, and experiential variables as causation. At this point there is no body of evidence that points to a sole cause for any childhood disorder. Much research remains to be done to sort out the relative contribution of these factors. NIMH is attempting to educate professionals and the general public at large through an integrated effort of information dissemination to provide up-to-date results of research and to correct counter-productive beliefs.

SCHIZOPHRENIA RESEARCH

Question: Schizophrenic disorders cost this country $20 billion a year, are financially and emotionally debilitating to the individuals afflicted and their families, are severe, pervasive and chronic. Over half the mental hospital beds in the country are occupied by patients suffering from a schizophrenic disorder. Yet only 13% of NIMH's research money is spent on schizophrenia research? Given these facts, why is not more of NIMH's resources applied to schizophrenia research?

While the NIMH budget reflects only 13% of research funds being spent directly on schizophrenia, much of the research in the basic neuroscience and behavioral science areas is relevant to the etiology of schizophrenia and the development of new treatment approaches for this illness. Thus the amount of research resources spent for schizophrenia exceeds 13% and is probably closer to 20%.

Due to the difficult nature of research in the area of schizophrenia, we have seen a decrease in the number of research applications and researchers who wish to conduct research in this area. There are problems in agreement on the diagnosis of schizophrenia as well as difficulties in studying an illness where there are so many concurrent variables such as exposure to medication and imminent danger of suicide. Also, recently with the advent of new research findings relevant to the affective disorders and childhood disorders, some investigators have turned their research interests to these areas. However, grant applications submitted in this area are funded at a rate consistent with research applications in other major mental health areas.

TARDIVE DYSKINESIA

Question: There are dangerous side effects such as tardive dyskinesias to continuous use of antipsychotic drugs. Also there is concern with the general poor level of functioning for many schizophrenic patients on drugs. What is NIMH doing to research these problems? To develop new more effective and safer drugs?

Anwswer: Tardive dyskinesia (TD) does pose a problem in the long-term use of antipsychotic drugs. Data now emerging from a prospective study of TD incidence suggest that the risk of developing TD following a four year period of exposure to antipsychotic drugs is about 1 in 10. The overall prevalence of TD among schizophrenic patients treated with antipsychotic drugs is probably around 20%. Further, many patients who receive medication over long periods are not restored to full adequate social functioning. In recent years, NIMH has supported and is currently supporting projects to examin two drug treatment strategies. One strategy is to provide antipsychotic medication to prevent relapse but at extremely low dosage to reduce the risk of tardive dyskinesia. The other approach is providing medication only when relapse threatens. Preliminary results suggest that both are promising drug treatment strategies.

The second avenue, to develop new more effective and safer drugs, is a more difficult undertaking. Since the discovery of chlorpromazine, any number of similar drugs have been developed but

despite claims of novelty from their developers they have generally proven to be "me too" drugs. Recently there have been important findings in neurotransmitter research (e.g., on the dopaminergic system) that could lead to the development of new and effective antipsychotic drugs that would not cause TD.

We do play a facilitative role once a promising compound is identified. Recently, a report appeared that a single injection of CCK, a gastrointestinal peptide also active in brain, provided dramatic improvement in schizophrenic patients for three weeks. We brought a group of investigators together to discuss this finding. Several of them are now studying CCK and one has already completed a replication study. Regrettably, the results are negative but the rapid examination of such new treatments is a high research priority.

Additionally, the Neurosciences Research Branch is increasing its emphasis on behavioral toxicology as a way of predicting adverse effect to psychoactive therapeutic agents.

COMMUNITY SUPPORT PROGRAM

Question: While the Administration has not requested a line item for the Community Support Program projects, has the money spent on this program in past years been well spent? What is the evaluation on the program?

Answer: Our national evaluations of progress in CSP States indicate that the program has stimulated a lot of progress toward its initial goals. CSP States have clarified State and local level responsibility for planning for the chronically mentally ill and have redirected or earmarked significant sums of mental health dollars for needed crisis, rehabilitation and case management services. They have also worked with other State agencies to develop housing and employment opportunities for the population. They have helped in establishing family support groups and expatient self-help groups, and they have provided needed technical assistance and training to a wide variety of agencies involved in services to the chronically mentally ill. One rough measure of the impact of the Federal initiative is an analysis of the pilot CSP States about two years ago, which indicated that for every NIMH CSP dollar, State mental health agencies participating in the program have earmarked $19 of State funds for community services for the population.

The true test of the program is whether it has helped develop organized service networks for the population at the local level and whether these services make a difference in improving the lives and productivity of the chronically mentally ill. Our evaluation results are encouraging. A study of CSP clients in 16 local sites operating according to NIMH guidelines indicated that after one year of participation in these systems, clients were spending 50% less time in hospitals than they had in all prior years since onset of their illness.

Question: Given the uneveness of the States regarding their services to the chronically mentally ill (more than half of whom now live in the community) and the fiscal squeeze confronting

States presently, should not the Federal government assist States to coordinate their services on behalf of the chronically mentally ill by continuing the NIMH Community Support Program?

Answer: It is our belief that the impetus given to the States by the demonstration program will be sufficient to assure continuance of the effective aspects of the program.

BIOCHEMICAL AND GENETIC RESEARCH

Question: Some scientists are quite certain that severe mental illnesses as well as alcoholism are traceable to biochemical and genetic causes. Is this reflected in the NIMH and NIAAA research efforts? What percentage for each is for biological research?

Answer: Approximately 65% of the alcoholism research budget and 60% of the mental health research is biological in nature. In both of these areas biochemical and genetic research represents a major research component. Biological, biochemical and genetic factors have been clearly implicated in the etiology of several mental disorders. The NIMH research programs and research training have traditionally supported a broad base regarding the etiology and pathogenesis of mental disorders. It has traditionally expressed its concerns with biological underpinnings in a variety of ways including: (a) virtually all of the intramural research programs of the NIMH focus on basic and clinical biological investigations of mental disorders and their treatments; (b) the Neurosciences Branch of the extramural program supports research which is entirely on the basic neurosciences underlying mental disorders; (c) the clinical research programs of the NIMH support genetic, biochemical and other biological investigations, of the etiology, cause and treatment of mental disorders in children, adolescent, adult and the aged populations.

A sizable portion of our alcoholism research efforts have also been concentrated on the identification of genetic factors and the delineation of the underlying biochemical mechanisms for alcoholism. Research to date has indicated that there is a genetic component of alcoholism. Recent studies have further demonstrated that there are subtypes of alcoholism. One such subtype is limited to males only and is transmitted from father to son in an incidence rate nine times higher than the general population. A totally separate form of alcoholism is found in both males and females, transmitted from parents at a rate three times higher than would be expected if the risk was not biologically inheritable. The establishment of a genetic underpinning for alcoholism necessitates, by definition, a biochemical basis for the disease. Information on the biological aspects of alcohol use has been obtained in NIAAA's Intramural Research Program through biochemical research into the processes by which alcohol is changed and interacts within the cells of the body and by which it effects the metabolic processes of the body. In addition to studying the effects of the metabolism of alcohol, a major effort is directed toward determining how the metabolism of the alcoholic differs from that of the nonalcoholic, and whether such differences are genetic or acquired, e.g., whether they precede or follow the excessive consumption of alcohol by an individual. Other studies are targeted to the elucidation of the

pathophysiologic basis of alcohol intoxication and abuse in order to provide research information relevant to the causes, processes, and treatments of alcoholism and alcohol-related problems. Investigations are directed toward the establishment of firm biological foundations upon which the actions of alcohol and their clinical relevance can be interpreted.

NATIONAL SPENDING FOR MENTAL HEALTH RESEARCH

Question: Why do we as a nation spend so many more dollars proportionately on cancer, heart and other physical diseases than we do on the serious mental illnesses?

Answer: It is only in the last several years that the ADM fields have developed the scientific base of knowledge, the methodology and clinical applicability to offer great potential for progress in the treatment of ADM disorders. This new knowledge along with recent revolutionary advances in research technology and theoretical concepts ultimately can contribute to reducing the tremendous economic cost and human suffering of ADM disorders. In recognition of this significant progress and potential the Administration has proposed relatively large real increases in the ADAMHA research budget in both 1983 and 1984. Although these increases will not put the mental health research investment on a par with that of other physical diseases, they must be tempered by the ability of the research field to respond with high-quality proposals and the need to consider overall increases in Federal expenditures.

STAFFING PROGRAMS FOR SEVERE MENTAL DISORDERS

Question: What is the staffing pattern currently, and what do you propose for staffing the severe disorder centers (schizophrenia disorders, affective disorders) to be able to launch and coordinate new thrusts in these areas?

Answer: The 1984 President's budget for NIMH increases its extramural research program by 12%. Included in the budget are over 300 positions to support the direct operations of the Institute. This level is adequate to handle the program increase, including any new monies associated with research on severe mental disorders.

Questions Submitted by Senator William Proxmire

EXTENT OF PROBLEM

Question: Dr. Mayer, I'd like to try to get a handle on what effect our investment in the fight against alcoholism and drug abuse has had on the problem. You say in your prepared statement that 10 million American adults are problem drinkers or alcoholics and more than 3 million American teenagers abuse alcohol. How do these figures compare with the numbers in these two categories five and ten years ago?

Answer: The Fourth Special Report to the U.S. Congress on Alcohol and Health, January 1981, estimates that 10 percent of the

U.S. drinkers or 10 million Americans can be considered to be problem drinkers as opposed to 8.6 million in 1975 and 7.9 million in 1970. With regard to teenagers, the Fourth Special Report to the U.S. Congress sets forth 1979 data that states that 29 percent of the senior high school students self-report drunkeness at least 6 times per year. Thus, there were 3 million of these students reporting drunkeness in 1980 as opposed to 2.6 million in 1975 and 2.2 million in 1970. This represents a percentage increase from 24 percent in 1970 to 29 percent in 1980.

DRUG USE AMONG AMERICAN YOUTH

Question: You also indicate that American youth still have the highest levels of drug abuse in any industrialized nation. Can you tell us why this is the case?

Answer: We cannot be certain about the reasons for the huge increase in drug taking by youth we expereinced in the 1960's and 1970's, but that increase can be correlated with a number of other features of that period. This was a period when children born during the post war "baby boom" entered and passed through the vulnerable years when experimentation with and use of drugs appears to be highest. There was actually a doubling of teenagers during this period. It was also a period of relative affluence, a time when a much larger number of young people decided to take advantage of expanded opportunities for education, and in many cases postponed the stablizing influence of marriage and career oriented employment. Also, the Vietnam conflict proved to be a focal point for disagreement with national policies and goals and a "lightening rod" for feelings of discontent.

Above all, perhaps, it was a period of rapid expansion in the substantial criminal activity required to successfully import and distribute drugs in a way that increased their availability for experimentation and use on a geographic scale never before seen in this country. Although it has declined somewhat in recent years, an unfortunately high level of drug use has remained a part of the American society.

DRUG USE FOR NONMEDICAL PURPOSES

Question: Dr. Mayer, in your prepared opening remarks you also refer to the fact that one-third of all Americans over 12 have used an illicit substance or a prescription drug for nonmedical purposes. How does this compare to the situation that existed five years ago?

Answer: In 1982, based on the results from a representative sample of our Nation's households, we found that about one-third of all Americans residing in households had used an illicit substance or used a prescription substance for nonmedical reasons. A strong indicator of the extensive use of substances for nonmedical purposes is marijuana use. NIDA's 1982 sample showed that thirty-one percent of individuals (in the sample) over the age of twelve had at some time used marijuana. Comparing this

figure with the results obtained five years earlier, in 1977, NIDA's similarly drawn sample showed that twenty-five percent of all individuals over the age of twelve had used marijuana. Thus, in the five years, from 1977 to 1982, there was a six percent increase in life experience with marijuana.

AVERAGE COST OF GRANTS

Question: The table on page 29 of your justification indicates that between 1982 and 1984 the average cost of a noncompeting extramural research project rose by $17,218 or 15.6 percent while the average price tag on a new project went up by only $7,876 or 7.9 percent. Can you give us some idea as to why the cost of noncompeting projects rose at twice the rate of new project costs between 1982 and 1984?

Answer: In 1982 in order to support a sufficient level of high priority new and competing grants, we reduced continuation awards on many projects from 5 percent to up to 15 percent in a few instances. We operated under that policy through most of 1982, since we could not anticipate the eventual supplemental research funds which we received in September of that year. In the 1984 budget we are again funding continuation costs at a figure more closely approximating the amount recommended for funding by the peer review committees, the amount we usually provide each grantee under normal circumstances.

ALZHEIMER'S DISEASE

Question: Dr. Mayer, in your opening statement you referred to your research into Alzheimer's disease. A report to the Committee by the National Institute on Aging in February indicated that you would spend $4,950,000 on this problem in fiscal year 1983. Can you tell us how much you will be spending in this area next year under your proposed budget and what total Public Health Service obligations will be?

Answer: In 1984 the NIMH expects to spend $5.6 million for research on Alzheimer's disease and the basic neurologic, cognitive and psychosocial precursors and concomitants of this condition, while total PHS obligations will be $25.7 million.

RESEARCH PRIORITIES

Question: On page 33 of your justifications you refer to depression as the most destructive group of mental illnesses in the United States in terms of prevalence, economic cost, impact on families, and mortality; yet at a time when you are proposing an increase of 33 percent in your budget for extramural research on stress and psychosomatic disorders you plan to increase your extramural research into depression and manic depressive illness by only 11 percent -- one-third as much. Why have you settled on these relative priorities?

Answer: The Public Health Service has a number of initiatives in the area of stress and psychosomatic disorders which necessitate the NIMH increasing the allocation of funds to

this area. These include an expanded emphasis on stress in the workplace with a focus on preventing the stress or training people how to cope with the stress in order to reduce negative health outcomes. Although depression may be a more serious illness, health problems
resulting from stress affect a larger number of Americans. For this reason the Public Health Service in general and the NIMH in particular are increasing efforts to understand the mechanisms by which stress triggers various physical and mental illnesses and to develop interventions which will prevent such effects. Further, it is a well established finding that various life stresses often preceed a depressive episode. It is hoped that by learning ways of avoiding or reducing the harmful effects of stress, episodes of depression may also be avoided.

CLINICAL TRAINING

Question: The General Accounting Office is currently conducting a review of the NIMH's allocation of clinical training funds in order to ascertain whether the various priorities proposed by the Committee have been receiving appropriate support. One issue in particular continues to be of considerable concern to the Committee. Even though for the past two years express language has been included emphasizing the importance of linking clinical training funds to the "pay back" provisions of the Mental Health Systems Act, the Committee continues to receive reports from the non-physician disciplines that a disproportionately small percentage of psychiatry funds are tied to "pay back" requirements. Accordingly, the Committee would appreciate NIMH's clarification of this matter.

Answer: Most psychiatry clinical training funds are awarded for teaching costs which, by their general nature do not require pay back, rather than directly to trainees where pay back is required for many reasons.

1. All residents in all medical specialities, including psychiatry, receive stipends while in training. Often these are generated from funds received for the delivery of the residents' services to patients. These stipend levels are higher than those permitted by PHS guidelines and thus the NIMH stipends, with their payback provision, are largely unnecessary and unpopular. In sum, there is not a demand for these stipends in psychiatry.

2. In medical schools faculty are required to "earn" a substantial part of their salaries through service delivery, research grants, consultation to outside agencies, or other means. This is true for psychiatry, but not for faculty in the other mental health disciplines, who receive full time salaries and whose students, unlike psychiatric residents, pay tuition. Thus for psychiatry faculty time spent in teaching must compete with the pressure to generate income from other activities. Also, since psychiatric care is usually delivered in the privacy of a one-to-one relationship, teaching cannot be done while delivering services, as it can by the surgeon, radiologist, or internist. Thus psychiatry departments need NIMH funds for teaching and supervision, which might otherwise not be

done. These funds permit work in public facilities with indigent patients, and thus indirectly pay for services to underserved populations.

3. In recent years approximately one-third of psychiatry clinical training funds have gone for the teaching of behavioral medicine and psychiatric skills and knowledge to general medical students. Additional grants have funded consultation/liaison programs which have educated primary care and other non-psychiatric residents and staff. In view of the evidence that in recent years over half of the individuals in this country with mental illness are seen solely in the non-psychiatric medical sector and not by mental health professionals in any discipline, we regard these training programs as crucial in the overall effort to improve the mental health diagnostic and treatment services provided to a large segment of the population. Teaching funds, not stipends, are needed for this initiative. This is a very cost-effective method. In fiscal year 1982, for example, almost 40,000 medical students received education in psychiatry at a cost to the government of less than $100 per student. Research has shown that the consultation-liaison programs are effective in reducing the cost of medical care, and the savings in unnecessary hospitalization and procedures far outweigh the cost of the program.

In summary, psychiatry training programs do not support many trainee stipends because the needs of that discipline are for teaching costs. Other disciplines differ, with psychology needing student stipends, and nursing having a balance of trainee and teaching support. State manpower development projects support no trainees, and innovative programs in research and demonstration and paraprofessional manpower development allocate very little for student support. The NIMH program has been flexible in responding to different needs in maintaining a balanced program and influencing the nature of training to respond to national priorities.

SAINT ELIZABETHS HOSPITAL

Question: Dr. Mayer, in your statement on Saint Elizabeths Hospital, you touched briefly on the hospital's patient care progress. For example, you cited an 11 percent reduction in the rate of rehospitalization for outpatients; an 8 percent decrease in admissions; a reduction in the average length of stay from 16 days to 11 days; and a drop in the inpatient census by approximately 6 percent since last year. This may be progress for the hospital, but what about the patients? My point is, do these percentages represent cures, or the fact that some patients may be receiving more drug therapy, or the fact that the hospital has reclassified its admission criteria? How did you accomplish these reductions?

Answer: The reduction in length of inpatient hospitalization, together with an increase in the length of time a patient remains in the community, reflect the hospital's commitment to deinstitutionalization through the practice of advanced mental health care. Deinstitutionalization recognizes the disruptive potential of prolonged hospitalization and the advantages of maintaining a person in as normal an environment as possible.

Through the increased use of crisis intervention services, and consultation and services to other care givers, the hospital has helped to strengthen the support services available to the mentally ill and thus prevent the need for hospitalization and rehospitalization. The admission criteria remain unchanged, although there has been increased attention to assure that the hospital's resources are used appropriately. Increased crisis intervention, together with prompt referral have prevented hospitalization. In addition, advances in the science of pharmaclogy have made available to the psychiatrist a large number of new medications which are much more specific to various symptoms and diagnoses. This has allowed the staff to treat the acute phases of illness more quickly than has been possible in the past, and to maintain the patient in the community more safely and confidently.

Question: Dr. Mayer, it has been reported to the subcommittee that patients in the John Howard Pavilion are allowed to make two free 10 minute telephone calls every day anywhere in the United States. We were advised that the hospital's Legal Department justified such policy on the grounds that any other action would impose a hardship on the families of these patients. If this information is correct, it means that on any given day the 330 patients housed in the Pavilion have access to a free phone courtesy of the U.S. taxpayer. Can you clarify this for us?

Answer: Patients are allowed to make two local telephone calls per day on government telephones. Long distance calls must be made collect. John Howard Pavilion is a treatment facility and not a prison and as such comes under the regulations of the Joint Commission on Accreditation of Hospitals which requires that patients have access to use of a telephone for private telephone conversations. We have explored the best ways to meet this requirement. The telephone company will install pay telephones only if they are guaranteed a minimum amount of collections. Since most of our patients are indigent, it is more feasible to have them allowed limited use of government telephones from a cost point of view and if we have a patient who abuses his/her telephone privileges, we can control who the patient is calling by having a staff member place the calls.

Question: On page 108, you show a net increase in Fiscal Year 1984 of $9,875,000 in 12 areas over the 1983 base. However, the justifications do not indicate a current funding level for each area. For example, in Fiscal 1984, the housing allowance cost for commissioned officers would increase by $32,000 over the 1983 base. What is this base and the other bases you have neglected to list?

Answer: The following information is provided in response to your question:

	1983 Base Amount	Change from Base Amount
Increases		
1. Annualization of FY 1983 Pay Raise and Pay Cap.....	5,184,000	+187,000
2. Annualization of Medicare Tax.....	717,000	+207,000
3. Annualization of Employee Health Benefits.....	-0- 1/	+123,000
4. Increased Variable Housing Allowance Cost for Commissioned Officers.....	381,000	+32,000
5. Within-grade increases.....	110,065,002 2/	+2,513,000
6. Payment to Office of Federal Employees Compensation....	1,259,000	+2,000
7. Postage.....	124,000	+6,000
8. Increase in utility and fuel oil cost.....	6,522,000	+130,000
9. Mandatory increases for Medical-Surgical Services Contract, Transitional Services Contract, and Implementation of Court Ordered Outplacement Plan.	5,480,000 3/	+418,000
10. NIMH Research.....	3,400,000	+170,000
11. Increase in cost of medical supplies, food and other patient costs.....	7,500,000	+534,000
12. Corporation Costs (including mandated billing system $1,800,000).....	--- 4/	+5,553,000
Subtotal.....	---	+9,875,000

1/ Increase in FY 1983 was absorbed.
2/ Represents total salaries and benefits from which within-grade increases are derived.
3/ This amount includes consultant services for A-76 review.
4/ New cost in FY 1984; no FY 1983 base.

The hospital plans to contract for a fully automated billing and collection system in 1984, and this accounts for $1.8 million of the $6 million increase. In addition, approximately half of the remaining costs associated with the corporation - or $1.9 million - are expected to fall within this object classification. Such costs would include payments for the Board of Directors and certain overhead functions currently supplied by the hospital's parent Federal agencies. The remaining $2.3 million reflects an anticipated shift from the use of in-house staff to contracts for the performance of certain support functions. Several hospital operations are currently being studied to determine whether they can be performed more economically by contract, and the results will be known in 1984. No cost offsets are shown for this last area, as most of the staff for the affected functions would be required for the major part of the year.

Question: Let us have a detailed breakdown of these expenses for the record.

Answer:

Corporation Costs.....	$3,753,000
Billing System.....	1,800,000
Increase in Contracts for Medical Services Transitional Services Contracts and Consultant Services for A-76 Review.....	338,000
	$5,891,000

Question: I am curious about the item noted on page 127 listed as "Sale of Scrap". You estimate reimbursement of $6,000 from these sales in 1983 and the same amount next year. What kind of scrap are you selling?

Answer: The hospital sells three kinds of scrap: silver, metal and rags. Used X-ray films and batteries is the source of silver. Old spare parts, lawnmowers, etc. is the source of metal, while rags consist of torn towels, sheets, and patient clothing.

CLINICAL TRAINING

Question: What non-Federal sources of funding for mental health clinical training, if any, have emerged to fill some of the gaps left by the phasing out of Federal support?

Answer: We have not to date conducted a systematic evaluation of outside sources of clinical training funds. Many students take out commercial or Federally insured loans so that they may continue their education, and some attend school part-time, while also working part-time. Training departments may negotiate with local service delivery agencies to see if they are able to help with the cost of training in return for services. The overall success of these methods in filling funding gaps is undetermined, however.

TRAINING MINORITIES

Question: How many minority persons were trained as mental health clinical personnel under your program in the last two years?

Answer: I regret that we have not been able to collect data on the racial or ethnic identification of students supported under our training programs, so I cannot provide a definite answer to your question. Since our clinical training programs do stress the recruitment of minority students and many grants are to minority institutions, I would estimate that several hundred minority students have received clinical training stipends in each of the last two years, and many more have benefitted from the curricula NIMH has supported.

Question: What percentage of the total numbers of persons receiving such training did they represent?

Answer: As indicated above, we do not have the data necessary to answer this question.

NUMBER OF MENTAL HEALTH PROFESSIONALS

Question: What is the current number of psychiatrists and psychologists and other mental health personnel in this country?

Answer: We estimate that there are now approximately 31,000 psychiatrists and child psychiatrists, 33,000 health service providers in psychology, over 30,000 mental health social workers trained at the graduate level, and over 7,000 master's level psychiatric nurses.

Question: What is the projected need over the next 10 years?

Answer: The types of existing shortages are widely agreed upon, but the extent has been documented only for psychiatry. The Graduate Medical Education National Advisory Committee (GMENAC) projected a shortage of 8,000 general psychiatrists and 4,900 child psychiatrists by 1990, in spite of an overall surplus of physicians. Many vacancies exist for psychiatrists in mental health facilities, and several hundred geographic areas throughout the country have been designated psychiatric manpower shortage areas. Vacant positions for psychiatric nurses also exist in mental health facilities, and a recent Institute of Medicine study recommended a rapid increase in the supply of nurses trained at the graduate level. Minorities are underrepresented in relation to their proportion in the population in all mental health specialities. There are extremely few geriatric mental health specialists in any discipline, and the shortages in this area are so great that the primary training effort at this time is focused on increasing the number of educators and trainers, so that programs of high quality may be established. For child mental health specialists the shortages are personnel to diagnose and treat the most severely mentally ill children and those most likely to be underserved (minorities, the abused or neglected, or residents of inner city or rural areas). It is in these areas that there will be the greatest need over the next ten years.

Question: What is the percentage of inpatients versus outpatients?

Answer: As of May 31, 1983, there were 1,788 (39%) inpatients and 2,792 (61%) outpatients on the hospital rolls, representing approximately a two to one ratio. The total outpatients includes 1,292 outpatients served by the Area D Community Mental Health Center, and the remainder (1,500) representing residents of the District of Columbia Catchment Areas A, B, and C, and outpatients being served from the hospital specialty programs, i.e., forensic, mental health program for the deaf, and alcoholism programs.

Question: Is Saint Elizabeths a long term facility?

Answer: SEH is not a long term care facility in the technical sense. Under Medicare and Medicaid regulations, a long term facility is a nursing care facility. For purposes of Medicare and Medicaid, the hospital is defined as an institution for mental disease which treats both short term and long term patients. Currently, the hospital treats approximately 600 acute, short term patients and 700 chronic, long term patients, excluding those treated in specialty programs (children, mental health program for the deaf, forensic psychiatry, and residential alcohol and drug abuse programs). Of the resident population treated in adult psychiatric divisions, approximately 300 patients require some form of nursing care at either the skilled or intermediate levels. Approximately 120 of these patients require nursing care only while

the remainder require nursing care and some form of chronic psychiatric rehabilitative care.

Question: What is the ratio of psychiatrists per inpatient population?

Answer: The ratio of psychiatrists, including interns and residents, per resident inpatient is one psychiatrist to every 21.8 patients. In addition, the hospital employs non-psychiatrist physicians to act as general medical officers to care for inpatients' medical needs; the ratio of general medical officers to inpatients is one general medical officer to every 125.6 inpatients. These ratios do not include patients and psychiatrists employed in the research division, the medical and surgical division, the admissions office and the training division.

Question: Your 1984 request under "Other Services" is more than 50 percent over the current funding level of $5,790,000. What is included in this account?

Answer: The large increase in "Other Services" in FY 1984 is caused by the initial cost of the proposed corporation which includes the fully automated billing system necessary to make the hospital make maximal use of reimbursements.

GERIATRIC MENTAL HEALTH

Question: Please supply the same information for persons specializing in the problems of geriatric mental health and the mental health of children.

Answer: As noted above, we have no firm figures on the supply of specialists in the mental health of children and the elderly. About 10 percent of all psychiatrists are child psychiatrists and as few as one percent are geriatric psychiatrists. About 10 to 15 percent of health service provider psychologists are child psychologists, and very few are geriatric specialists. Specialization is even rare in social work.

These percentages are far below the proportion of the total population which is made up by children and the elderly. Not only do we need many more specialists in these areas, but knowledge of how to treat these age groups must be more prominently included in the general basic professional curriculum.

COMMUNITY SUPPORT PROGRAM

Question: What became of the old National Institute of Mental Health Community Support Program?

Answer: The Community Support Program (CSP) is active in 1983. Its $6 million budget will be allocated as follows:

- To 25 States, the Virgin Islands and Puerto Rico eligible for noncompeting continuations of their CSP demonstrations.

- To 11 of these States in their fifth and final year of funding of their CSP demonstration project.

- Supplements to 4 of the CSP States currently receiving noncompeting continuations to study the extent of and the needs of the homeless mentally ill.

  For technical assistance program for existing and new projects will also be continued.

- To an additional 6 States with previously approved new or competing applications.

- To 3 other new States of the remaining 8 States that have never been funded.

- For 7 research grants for investigation of State mental health service system issues impacting on the chronically mentally ill.

Support for the CSP demonstration program is not contained in the President's budget for Fiscal Year 1984.

Applications received proposed to study such areas as: assessing the demography of and State mental health service delivery systems for particular subgroups of chronically mentally ill persons including the homeless, the young adult, children, and elderly; structure, operation, client outcome and cost effectiveness of various service system components including psychosocial rehabilitation, varying levels of residential care, case management, and partial hospitalization; and identification and analyses of the effects of Federal and State fiscal and admnistrative policies on the delivery of hospital and community services to the population.

Question: What needs to be done to assure that chronically mentally ill persons released from institutions receive adequate outpatient care and followup in their communities?

Answer: To supplement existing (or non-existing) mental health services in any given area, there needs to be developed a series of interlinking support programs to assist the mentally disabled in:

- Adequate funds from employment, welfare and/or entitlement.

- Help in securing food, clothing, shelter, and other daily living needs.

- 24-hour emergency service.

- Prevocational and vocational development.

- Referrals to other services or entitlement programs.

- A range of housing alternatives.

- Transportation for access to services.

- Social and recreational activities.

- Backup support assistance, consultation and education to families, friends, and employers.

- Case management activities to coordinate client assistance.

DUPLICATION OF RESEARCH SUPPORT

Question: What kind of liaison with other research agencies is maintained to avoid such duplication of effort?

Answer: All applications to the Public Health Service come through a central receipt point, the Division of Research Grants. This system provides assurance that aplications are assigned to only one Institute for funding so that duplication is not possible. As a further check, staff of related programs have contact with one another, share information about current research holdings as well as about future plans. Under certain circumstances when both Institutes have an interest in the same application, joint funding is possible so that each Institute funds a specified portion of the research proposed.

SOCIAL RESEARCH

Question: Has the National Institute of Mental Health completely phased out support for the so-called social research as proposed a year ago?

Answer: The Institute continues to support social science research which focuses directly on the effects of certain social phenomena, relationships and processes on mental health and illness. For example, the studies of crime and family violence in relation to mental illness, and the influence of cultural values on utilization of mental health services are important issues. Additional examples of types of projects that will continue to be funded include: (1) behavioral/mental dysfunction among children of divorced parents; (2) job adjustment skills for former mental patients; and (3) psychosocial stressors and coping mechanisms among minority populations.

Question: What indications are there, if any, that support for this kind of research has been taken up by non-Federal resources?

Answer: There is no information to date on the extent to which social research in areas not funded by the Institute has been supported by non-Federal sources.

PROMISING RESEARCH AREAS

Question: Which of the research areas you are supporting holds the most promise for significant progress in the prevention, diagnosis, and treatment of mental disorders?

Answer: Research in all the priority areas, that is, schizophrenia; depression; mental disorders of the aged; childhood disorders; anxiety disorders, stress and psychosomatic disorders, basic studies of brain and behavior; epidemiology; prevention; the special problems of minorities; and environmental disasters are all

contributing to increasing the knowledge base that will significantly enhance progress toward the prevention, diagnosis, and treatment of mental disorders.

PREVENTION RESEARCH

Question: What kinds of research do you support for the prevention of mental illness?

Answer: NIMH is emphasizing the following five prevention research areas:

Question: What research or demonstrations does NIMH support, if any, to discover better ways to care for chronically mentally ill persons released from institutions into the community?

Answer: In Fiscal Year 1982 the Congress authorized the NIMH to allocate a portion of its Community Support Program (CSP) budget for research and evaluation of the care and treatment of persons disabled by chronic mental illness. The NIMH allocated approximately $1 million for research related to the goals of the CSP. In particular, monies were directed to accomplish the following:

- to analyze and disseminate lessons learned to date from the Federal CSP pilot program and similar efforts in non-CSP States;

- to develop and disseminate information on costs and benefits of community support system approaches for use in program planning and policy-making;

- to improve treatment and/or rehabilitation methods and techniques impacting on persons disabled by chronic mental illness;

- to investigate the efficacy of various models of service delivery, staffing mixes, organization, and funding; and

- to develop linkages among researchers, planners and direct service workers to encourage further research which will be more "user" oriented.

Cutting across these objectives are the broader goals of disseminating existing information/knowledge of CSP activities or developing and disseminating new information/knowledge.

Question: What is the National Institute of Mental Health doing to study the effects of deinstitutionalization on patients and the communities into which they are released?

Answer: In Fiscal Year 1983, the NIMH developed a research grant program on State service system research on the chronically mentally ill. This program is intended to target funds to develop generalizable knowledge to improve Federal, State and local planning, policymaking and program management relative to service delivery systems for chronically mentally ill individuals.

Activities to be supported must be of critical importance to State decisionmakers and/or Federal policymakers with responsibility for planning, organizing, managing, and financing services systems for the population.

This initiative encouraged applications from States in collaboration with universities and required that all applicants focus their efforts on research in which service delivery systems across States would result in findings which would be generalizable to other States. Forty-six applications were received under this announcement.

1. Prevention-Intervention research centers.
2. Ways of reducing stress in the workplace.
3. Work as therapy for the social rehabilitation of deinstitutionalized mental patients.
4. Reducing the stigma and resistance to mental health services.
5. Risk factors. Ultimately, prevention and effective treatment of disorders result from understanding the causes of the illnesses and those things that put people at risk for mental illness.

MINORITY RESEARCH

Question: What research do you support on mental health issues particularly relevant to minority populations?

Answer: Research on all major racial and ethnic groups is supported across a broad spectrum, and includes studies in the behavioral sciences, clinical and treatment problems, services, and the prevention of serious disorders. Some examples of projects currently funded include studies of:

- Black males at risk for low life expectency.
- Early intervention program for Black children.
- Psychiatric treatment of Chicano patients.
- Institutional racism with child welfare.
- Two national surveys of Black and Hispanic Americans to study utilization of mental health services, mental health impact of chronic unemployment, and the role of church, family and friendship systems in the prevention of mental illness.

In addition, there are five research and development centers that represent a major research program for the Hispanic, Black, Asian, and Native American populations.

MENTAL HEALTH RESEARCH FOR THE ELDERLY

Question: What research do you support on mental health problems related to the elderly?

Answer: The NIMH has a broad spectrum of research in developing an understanding of and in developing effective treatments for the problems of the elderly. The NIMH extramural program emphasized research on: (a) causes, treatment, and prevention of Alzheimer's disease, senile dementia, and related disorders; (b) causes, treatment, and prevention of depression in

older persons; (c) psychopharmacology; (d) physical illness and mental disorder in later life; (e) chronically mentally ill elderly; (f) treatment intervention, clinical trials, and service delivery models for the elderly; (g) prevention of pathology among elderly at risk for mental illness; (h) geriatric mental health academic awards for the support of teacher/investigators in psychiatry and psychiatric nursing.

The NIMH intramural research program is involved in basic and clinical research on Parkinson's disease, senile dementia, and Alzheimer's disease.

DUPLICATION OF EFFORT

Question: How does the Department of Health and Human Services guard against duplication of mental health-related research supported by the National Institute of Mental Health and by other Federal research agencies, such as the National Institute of Neurological and Communicative Disorders and Stroke in the National Institutes of Health?

Answer: All applications to the Public Health Service come through a central receipt point, the Division of Research Grants. This system provides assurance that aplications are assigned to only one Institute for funding so that duplication is not possible. As a further check, staff of related programs have contact with one another, share information about current research holdings as well as about future plans. Under certain circumstances when both Institutes have an interest in the same application, joint funding is possible so that each Institute funds a specified portion of the research proposed.

CENTERS FOR DISEASE CONTROL

STATEMENT OF DR. WILLIAM H. FOEGE, DIRECTOR

ACCOMPANIED BY:

JAMES D. BLOOM, EXECUTIVE OFFICER
DR. JOHN D. MILLAR, DIRECTOR, NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
DR. WALTER DOWDLE, DIRECTOR, CENTER FOR INFECTIOUS DISEASES
ANTHONY ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET, HHS

OPENING REMARKS

Senator HATFIELD [presiding]. We will now turn to consideration of the budget request for the Centers for Disease Control, a hearing I especially look forward to each year for a variety of reasons—principal among them because of the outstanding testimony and presentation given by Dr. William Foege, CDC's distinguished Director for more than 6 years.

Earlier this month, Dr. Foege requested that he be relieved of the responsibilities of Director to enable him to focus more deeply on specific priority areas within CDC's jurisdiction—such as CDC international health projects and the Centers' relationship with academia. This, then, will be his last official appearance, as Director, before our committee.

Dr. Foege is a public servant of the highest order and a man whose vast knowledge in the field of public health is equaled by his great compassion. He has dedicated most of his life's work to the public health mandate of the Centers for Disease Control, and he can be quite proud of the many accomplishments achieved under his stewardship.

Most important perhaps is the great progress we have made in the area of childhood immunization where we have achieved an immunization level of 95 percent. We are close to achieving the complete eradication of measles as well.

It is with great regret that we acknowledge your leaving, but it is also comforting to know that you will continue to give of your expertise and vision, without which CDC and the Nation would suffer a great loss.

With that said, let us now turn to the task of discussing the specifics of the fiscal year 1984 budget for the Centers for Disease Control.

And if you would please present your colleagues who are with you this morning, you may proceed to summarize or highlight your testimony.

We will place the entire statement in the record.

INTRODUCTION OF ASSOCIATES

Dr. FOEGE. Thank you, Mr. Chairman, for that nice introduction.

On my far right is Mr. Tony Itteilag, who is the Deputy Assistant Secretary of the Budget.

Next to me is Dr. Millar who is the Director of NIOSH.

On my left is Mr. Jim Bloom, CDC's Executive Officer.

And to his left is Dr. Walter Dowdle, the Director for the Center for Infectious Diseases.

Senator HATFIELD. We welcome each of you.

Dr. FOEGE. Thank you for the opportunity to summarize our statement.

I think the story of public health in 1982 continues to be one of gratifying successes on the one hand, but on the other hand a background of missed opportunities and unsolved problems.

I would like to say something about both the good and the bad side, but to start with, the successes. We think the foundation of public health is social justice. And I was happy to hear your remarks on immunization because I believe we are coming close to social justice in the United States with immunization.

This past year the percentage of children immunized at the time they entered school increased to between 96 and 97 percent. And the incidence of disease has gone down accordingly.

In the last decade, we have had fewer cases of polio in all 10 years together than we used to have during a single day in the 1950's, an unbelievable accomplishment.

Senator HATFIELD. A single day?

Dr. FOEGE. Single day in the 1950's, during epidemic periods.

When my father was born, the third leading cause of premature death was diphtheria. Last year, we had only three cases in the entire country in the entire year.

You mentioned the decrease in measles. Forty percent of all our cases last year were directly due to importation. And we have in this country now some 16,000 children who are growing normally who would have been retarded if not for the measles program in the last two decades. Some 5,000 children are alive who would have died because of measles in the last two decades.

So this has been a tremendous accomplishment. We have come a long way.

[Chart.]

As you can see, measles morbidity, even in the last few years, has come down dramatically.

The next chart.

[Chart.]

While we have a long way to go to actually control gonorrhea, I think it is very encouraging. There has been a decline in the gonorrhea rate of 10 percent in the last 4 years.

With tuberculosis, the rates of tuberculosis have been leveling in recent years. In fact, in 1980, an increase was noted in our earlier hearings.

In 1982 tuberculosis again declined about 5 percent as compared to 1981.

We have had an opportunity for a fresh start in NIOSH this year for which we are extremely grateful. We now have the ability to summarize the 10 leading occupational health problems. Two years ago, we did not know this.

The fact that we can prioritize and summarize allows us to put increased emphasis in certain areas. We are, again, increasing the number of criteria documents and the current intelligence bulletins. There is new emphasis on quality science in NIOSH. And, indeed, the lead investigator on the West Bank right now for the investigation of problems that are being seen in Palestinian children is a NIOSH scientist.

We have seen improvements in lifestyle in the last year—decreasing smoking rates, increasing exercise rates. Twenty States now have child restraint laws for young children in automobiles. We are beginning to grapple with the problem of drinking and driving in this country.

There has been a decrease in infant mortality.

We can show now some results from the diabetes program. In Maine, Rhode Island, and Colorado, they are now able to show a 30-percent reduction in hospitalization rates for diabetics during the year after patients are provided with an educational program. We are able to see in some Indian groups now an actual reduction in complications of diabetes with aggressive therapy of hypertension.

It has been an exciting time in public health.

The other side of the coin is that children continue to be the innocent victims of sexually transmitted diseases. We lose about 500 newborns a year to herpes who die because they contract herpes during the birth process. About 250 newborns are retarded each year because of herpes. Thirty thousand newborns develop a pneumonia due to chlamydia which they acquire during the birth process.

Congenital syphilis is increasing in this country after years, and, in fact, decades of decreasing.

One thousand times a day, an American dies prematurely because of cigarettes. We simply haven't learned how to deal with this modern-day epidemic. I am afraid over the long run, it will be not understandable that we had all this information about cigarettes and still allowed an industry to spend over $1 billion a year to promote smoking.

Thirteen thousand workers die each year at work because of accidents. And, surely, a great deal of this is avoidable.

While we point with pride to the fact that we are achieving social justice in immunizations in this country, the leading cause of childhood mortality in West Africa is still measles. We haven't learned how to deliver childhood immunizations around the world.

Of the unsolved problems, surely, the one that is most on our minds at the present time is acquired immune deficiency syndrome. We have had 1,300 cases reported. And of this number, 500 have already died. And these are primarily young people in their twenties and thirties.

We are now having five to six new cases reported each day. We have learned a great deal about who is at risk—namely gay men, IV drug users, Haitians for reasons that we don't understand, hemophiliacs, the children of AIDS cases, the spouses of AIDS cases, and perhaps people who receive blood transfusions.

We have learned a great deal about the spread, that certain sexual practices are causing spread, as well as certain blood products. And we have even learned enough to be able to make recommendations on how to decrease the risk.

Nonetheless, if we were able today to stop all transmission of AIDS, there are still probably 1,500 people who are in the incubation period who over the next 12 to 14 months would develop AIDS. The majority would die within a few years.

We don't have the agent. We are quite certain that it is a virus. Until we get the agent, this will understandably cause concern and even terror in certain groups. If you talk to the gay population in New York City, they are terrorized by this disease.

You have heard both sides. On balance, though, the public health has improved significantly in the last year.

I would be happy to answer questions.

Senator HATFIELD. I have a lot of questions, but before I begin them, I would like to start with the bottom line.

First of all, the chairman of our subcommittee, Senator Weicker. Do you have questions?

Senator WEICKER. No, Mr. Chairman. It is nice to have someone taking over the wheel of the ship here after several weeks.

Senator HATFIELD. I know no man has spent more hours in subcommittee work and who is more dedicated to the subject field than Senator Weicker, the distinguished subcommittee chairman.

PREVENTIVE HEALTH RESOURCES

Could you give us an overall response to this matter of the relationship of funding to the problems that you are dealing with? We have sort of a general prevailing viewpoint around the political center here in the Nation today that the more money you put into defense, the more security you buy. They equate dollars to security, which I think is a false conundrum, but it is certainly one that prevails.

Second, we really understand, I think, that for every dollar we invest in preventive medicine, we can calculate we are gaining a $13 return in our economy. And there is a cost/benefit ratio that is the highest of any dollar we put in any agency or any program.

Now, with those two premises, dollars equate to better medicine or better health, or because of the cost/benefit ratio, the dollars we do put in, my question is: Basically, what is the projection of what we really need in this field? And are dollars the key, or is it trained personnel, more research, or wherein is our present weakness in attacking this with even greater vigor than what you have already been doing?

Dr. FOEGE. It is a difficult question to answer for many reasons, but I think in this country, we have a problem that is so basic that we tend not to even look at it. And that is that preventive medicine and curative medicine are held to different standards. Therefore, we can never get the right ratio with our present system.

It has nothing to do with political parties. It is true of every country in the world with the exception of one. For example, if a surgeon develops a new surgical technique, the surgeon has to show that there is some safety involved or it won't be allowed. But once having showed that, one does not even have to show it is efficacious. It is immediately funded by third-party insurance, by Government programs.

If you go a step beyond that to antibiotics and drugs, our laws say it has to be safe and efficacious. But once it passes those two tests, then it is automatically funded, again, by third-party payment and Government programs.

Prevention on the other hand—and you can use measles vaccine or polio vaccine as an example—has to show it is safe and efficacious, but then it has to show it has a positive benefit cost ratio which you don't have to show with curative programs.

But even after you show that and can demonstrate that a dollar invested in polio programs will save $10 you have to justify it every year. If that isn't enough, you have to justify it against other programs that have positive benefit cost ratios.

I don't see a way for prevention to ever get the same kind of attention as curative medicine because it is held to different standards. Curative medicine at most is held not to a benefit cost ratio, but a cost-effectiveness ratio.

You make a decision to have a 200-bed hospital. Then ask, what is the cheapest way to get that? The only exception I know of in the world, and that's why I am not very optimistic that this will easily be changed, is China where they did in fact put their rhetoric and their budget into prevention.

In 30 years' time, China went from third-world rates of births and deaths and disease to essentially first-world rates. They did this with a fraction of the cost or fraction of the budget that we have put into health.

I also think that prevention money——

CURATIVE AND PREVENTIVE MEDICINE

Senator HATFIELD. Excuse me. Before you move on, wherein are these inhibiting forces, these obstacles that create this dichotomy? I mean, especially in the light of our savings out of polio. Here is a prime example of what this Nation—what is it, $3 billion that we have saved by the preventive work of polio vaccine? We know pretty clearly what would happen if we could control the glucose levels in the diabetes area, of what the dollar value of preventive medicine could do there in terms of enhancing our economy.

We have those factual indisputable records. Now, what are the forces that put you into that kind of a dichotomy of curative medicine and preventive medicine and the distinguishing of those standards?

Dr. FOEGE. I think it is twofold.

One is that is the way we all live. That is, if you do surveys, you find that people fear cancer about as much as anything. And yet, a third of all cancers in this country are totally preventable.

I am not talking about good treatment; they are totally preventable. Despite the fear people don't live that way. But the day a person discovers they have lung cancer, they would give up everything they have if they could move back 2 years and practice prevention.

So we live in a way that permits us on one plane, an intellectual plane, to know what we should do, but on an emotional, day-to-day plane, we don't do it. And I think that gets into this.

Senator HATFIELD. We give all of our children polio vaccine as a preventative.

Dr. FOEGE. I am not sure that that would happen if a few wise people had not made this a school-entry requirement. Because 6 years ago, we were down to polio immunization rates of about 60 percent. Parents forget even with the best intentions. We know what to do, but that is not the way we live on a day-to-day basis.

Senator HATFIELD. It is a cultural thing.

Dr. FOEGE. That is part of it.

The second is just the institution. It would be nice if we would have an independent group such as the Office of Technological Assessment be able to say in which areas can we prove a positive benefit cost ratio. In many areas, we can't. We practice prevention because of a quality of life, not because we can show a dollar return.

But it would seem in the areas that we can actually show a dollar return, an independent group could say what the return will be; this would be optimal funding. And then that would be automatic rather than have to be repeatedly justified.

It seems to me that would be a preferred way. Otherwise, if you have a positive benefit cost ratio and you decide not to fund it adequately, you have already made a decision to pay more for that disease and increase human suffering.

I would like to say that is a classic example of fraud, waste, and abuse.

OFFICE OF TECHNOLOGY ASSESSMENT

Senator HATFIELD. Would that be reformed under the aegis of OTA or would it be expanding their budget or whatever requirements they would have to develop the capability, or would that be the logical location for that type of thing?

Dr. FOEGE. I think it would be. They have already done such studies on influenza vaccine, for instance. And I think this would put it in the control of Congress to come up with an independent assessment.

Senator HATFIELD. Would you have somebody on your staff prepare a review of the Organic Act of OTA to see if we have to amend it or if we would merely have to give that as an assignment with appropriate funding? Why not attack that problem?

Dr. FOEGE. I would be happy to. I think it is worth an attack.

[The information follows:]

CONGRESSIONAL REVIEW OF PREVENTION PRACTICES

The Office of Technology Assessment (OTA) would be a logical institution to do an independent policy review of optimal prevention practices (provider services and health education counseling) in the United States. We believe that the problem can be attacked by building on the model in the Social Security Amendment Act of 1983 (Public Law 98–21) developed by the Senate. Under title VI, section 601 of this act a commission would be established to assess the safety, efficacy, and cost effectiveness of medical and surgical procedures and services for this medicare program and make recommendations to the Secretary and the Congress. The OTA would provide oversight of the Commission's activities. A two-tier policy review process is envisioned whereby the Commission would make recommendations with respect to the optimal scientific packages of prevention services and the OTA would make recommendations to the Congress on levels of prevention funding.

This could serve as a model to create a commission to determine which prevention programs have a proven positive benefit cost ratio and should be excluded from the normal budget justification procedures. Periodic reviews of these programs by the Commission would determine whether such exclusions should be continued. Recommendations to Congress on funding levels would be provided by OTA. New authorities for OTA are probably not needed.

BARRIERS TO PREVENTION

Senator HATFIELD. What you are saying is we respond probably more on the dollar side basis than we would on some of the other cultural basis.

Dr. FOEGE. There are two real barriers to prevention.

One is the time between the act and the benefit. And the longer that time, the more difficult it is to get a prevention program.

If someone comes in with a fracture, it is very easy. The time between the action and the benefit is immediate. With polio vaccine, the benefit may be 10 or 15 or 20 years down the road. With smoking, it is 20 or 30 years. So the longer the benefit time, the more difficult the action.

The other barrier is the distance between the person making the decision to do something and the receipt of that action which is why international health programs become difficult to sell and to fund. But when you put the two together and you are talking about what to do with radiation waste or chemical dumps which may affect our children in two generations, our grandchildren, or people in the Third World, those become the most difficult decisions to make in public health.

AIDS PROBLEM

Senator HATFIELD. You mentioned something a while ago in reference to the AIDS problem. You said that the gay community in New York City particularly was terrified. What is the basis? How do you assess

that attitude or that terror today in relation to prevention or control or whatever? Is that an asset to the controlling of the problem or is there some way to explore that psychological view that they now hold to reduce this problem?

Dr. FOEGE. I believe that that is already happening. We have included representatives in the gay community in our scientific sessions so that anything that is decided immediately is conveyed to that community.

We are told that the actual habits are changing in the New York gay community. That is, the average AIDS case that we have studied has had contact with 60 different men in the past 12 months. And many of these contacts have been anonymous—in gay bars or bath houses. We are told that this lifestyle is already changing in New York City because we are quite certain that the risk of AIDS decreases if you decrease the number of contacts you have, and particularly decrease anonymous contacts.

I think that that is already changing.

Senator HATFIELD. So in other words, this is another example of public attitude or public view being used to help try to deal with the problem.

Dr. FOEGE. That's right.

PUBLIC ATTITUDE ABOUT SMOKING

Senator HATFIELD. But now, what do you find, though, in a public sector of attitude and feeling about smoking? Any difference?

Dr. FOEGE. One of the real problems with smoking is that people do not give informed consent. Our children begin smoking at a time when they are doing it for reasons other than that they really want to smoke—for instance, peer pressure. By the time they have decided they want to stop, they can't because they are truly addicted.

I have real sympathy with the smoker. And I do not attack smokers. I do attack the tobacco companies that will spend $1 billion a year trying to lure my child into smoking. And at least for a short period of time they were successful with my oldest child.

I take that very personally that they are spending $1 billion a year to say that I can't understand scientific facts, and that they are telling my child that I can't understand scientific facts. They are making it appear to be something it isn't. I think that it would be appropriate to stop cigarette advertising in this country.

I think it would be appropriate to increase the taxes to compensate for the medical costs because the costs of cigarette smoking to the medical industry are very large. What they in fact do is reduce the amount of resources available for nontobacco related illness.

Senator HATFIELD. I am glad you have such a Christian attitude toward smokers. As a reformed smoker, I have less. There is nothing more obnoxious than the reformed—especially when I am fighting with my daughter.

Dr. FOEGE. I can tell you how to get a teenager to stop smoking.

Senator HATFIELD. Will you?

Well, let me not stop there, then. I have a teenager whom I am trying to——

Dr. FOEGE. When my older son was 15, I asked what it would take to keep him from smoking. And he said a personal note from the Surgeon General. So I arranged to get a personal note from the Surgeon General as well as one from the equivalent of the Surgeon General of the U.S.S.R., which I presented to him.

It made no difference at all. At 18, he said to me, I wish smoking would not be so important to you because there are times I would like to stop.

But at age 20, as I picked him up after his first year of college in North Carolina, I noticed after a couple of hours of driving that he wasn't smoking. And I said, "You are not smoking."

He said, "I had to quit."

I said, "You had to?"

He said, "In North Carolina, they promote the tobacco industry to the point that the Governor gets on television to say how many jobs it is creating. The only way you can rebel in North Carolina is to stop smoking."

PREVENTIVE HEALTH SERVICES BLOCK GRANT

Senator HATFIELD. In other words, I have to shift my daughter from Boston to North Carolina.

Let me turn to a few other things. First of all, to the preventive health service block grant and a series of questions here.

What specific sources now exist which provide us with information as to States' uses of the preventive health service block grant funds?

Dr. FOEGE. We still have no way of assessing what is actually done in the States with preventive health block funds. There is no systematic surveillance system on how they are used. That, of course, is part of the act itself that we will not require systematic reports.

Senator HATFIELD. Would you review that? Do you think it is important to review that policy in terms of the success of the programs? Somehow, I see the philosophy behind it, but is that philosophy really justified by this policy?

Dr. FOEGE. I think the State health officers themselves are becoming concerned that they do not know what is happening in adjoining States. The Association of State and Territorial Health Officers has been asking the question how they could develop an information system.

That shows there is a need for that kind of information; but I am not sure how best to get it.

Senator HATFIELD. I am working now on a pilot project for a data center for library and warehouse information, something which would have a central location of, say, a medical center, an education center, where that data can be obtained from that center by practicing physicians, by hospitals, by clinics, by any number of users of that, beneficiaries of that information.

And at the same time, we will be able to draw out of that similar cases that are confronted by other physicians looking at a particular case.

It seems to me that we need to share more or provide facilities in which we are able to share the individual experiences that surgeons would practice in institutions throughout the country.

I just raise the question; I don't have the answer. It seems to me it pays to be on the board of the American Cancer Society, the various funding of projects hither and thither and everywhere, one giant computer where they could all be tracked down.

Project A over here might have an *x* factor they are looking at. Project C over here has a different *x* factor. But together, they might provide some mutual benefit to each other.

I don't know. It is too simplistic perhaps, but at the same time, I wonder if by taking advantage of our experiences, or our information, it might be comprehensive.

Dr. FOEGE. I think you are absolutely correct. There is no way that an individual—even with a library can have access to what is actually applicable to their problem. I think the closest we have come to doing this correctly is in the toxicology field where we now have many different data bases in toxicology. If a train derails, one has to very quickly be able to determine what is the chemical, but also what are the things that should be done.

There is a program now that the National Library of Medicine has put together with help from superfund and other places to have a computer that links all of the different toxicology data bases now.

So I think we are making some steps in that direction. But you are absolutely right, we have to use the technology to do a better job.

Senator HATFIELD. Dr. Foege, I think we have got a little too personal in this concern this morning. We are going to have to speak up a little bit more for the reporter.

Dr. FOEGE. Sorry.

1990 PREVENTION OBJECTIVES

Senator HATFIELD. I am still intrigued by what we are talking about.

Also, we run into purely the accountant's perspective, too, on these things where Federal funds are involved. We ought to have some ability to make a judgment or assessment of the utilization, the wise utilization, of those funds. And I think that is another dimension to this whole reporting problem, reporting policy.

Dr. FOEGE. I think another reason is that we have in this country—as we discussed last year—a national prevention strategy that includes 1990 objectives as a road map to know whether or not we are moving in the right direction, how close we are coming to those objections. For this one needs a reporting system that is fairly standardized.

Senator HATFIELD. Are we able to prioritize or have a priority list of such activities that are funded in this program or is that still something fairly decentralized?

Dr. FOEGE. It is somewhat decentralized. However, as you see now, in occupational health, we have a priority list.

Senator HATFIELD. That has emerged out of the compilation of the data from these various areas of training?

Dr. FOEGE. That's right.

Senator HATFIELD. That is something you have set in the priority, but this is what has emerged as what we find to be the reality.

Dr. FOEGE. We took the most knowledgeable people and had them look at the incidence, the severity, of a problem, and how amenable is it to correction, and through such a process then evolved the top priorities. But it was using information available.

Senator HATFIELD. I believe last year, you indicated there were four States who were not participating in this block grant program. Are all States now involved?

Dr. FOEGE. All of them are now participating.

RAPE PREVENTION

Senator HATFIELD. How would you assess the rape prevention program? Are the funds for prevention and services being fully utilized to the best of your knowledge?

Dr. FOEGE. Again, we don't have specific information, but that is one part of the block that is actually determined ahead of time that people have to spend a certain amount. But I can't give a good judgment on whether it is well used.

FLUORIDATION

Senator HATFIELD. Let me turn to an old one, fluoridation. Do you feel that you are still providing an important service to the States, the technical services assistance to the States in the area of fluoridation? Do you consider that a high priority or important necessity?

Dr. FOEGE. Very much so. In all of public health, this has about the highest benefit cost ratio that we know of. A dollar invested would save about $50 in dental health care delivery.

We don't have good information on what is happening in the States in terms of putting in new systems, but I think the assistance, the technical assistance, that we are providing is crucial.

Senator HATFIELD. You have funds for that in the budget for 1984?

Dr. FOEGE. We have no funds in the budget. Our intent is to continue a small core group, however, that would maintain some continuity of expertise in the area.

Senator HATFIELD. Did you request funds, and were they deleted by OMB or did you just not request funds for this project?

Dr. FOEGE. I would have to look back and see.

Senator HATFIELD. Would you provide that for the record?

Dr. FOEGE. Yes.

Senator HATFIELD. And if you did request funds, give me the figures as you requested them. Because if you have this kind of priority then the funds do not reflect the kind of importance you placed on the program.

And I would like to know what was your original request of OMB? That is my request so it protects you with your relationship to OMB.

Dr. FOEGE. I don't need a lot of protection any more.

[The information follows:]

1984 FLUORIDATION REQUEST

The budget request to OMB reflected the administration's position that fluoridation activities were included in the preventive health and health services block grant.

MOVING TO BLOCK GRANT FROM CATEGORICAL GRANT

Senator HATFIELD. Do you know of any States that have eliminated or greatly reduced their programs by moving to the block grant from the categorical grant?

Dr. FOEGE. In fluoridation specifically?

Senator HATFIELD. Yes, in fluoridation.

Dr. FOEGE. One survey that has been done outside of Government, but was reported recently, looked at 36 States. And as I recall, 20 of them were continuing at about the same level. Six had eliminated funds. In two of those six, there may have been a good reason that they had pretty well saturated the number of communities in their State, but at least four of them had eliminated funds while there were still fluoridation needs.

In five of them, there were some reductions. And in five, there was no response. It was difficult to judge. It is a mixed picture.

Senator HATFIELD. Dr. Foege, I believe that I have read where dental work is usually one of the first needs to be eliminated of families facing economic stress or economic problems. We have been and continue in many areas of this country to be in a severe recession, although there are many indications of an upturn.

But would this not also be another factor for at least the program being maintained to slow down those serious dental problems that people are going to pose upon or neglect during a period of economic stress? Doesn't that give more importance to this kind of program?

Dr. FOEGE. I think it does. And only about half of the U.S. population is actually drinking fluoridated water. So that means that over 100 million people are not being protected.

And you are right, we will continue to pay for that in the out years.

AIDS FUNDING

Senator HATFIELD. Going back to the AIDS program, I believe that $2 million was specifically provided by the Congress for the fiscal year 1982 program. How much will CDC actually spend on the study, surveillance, of this program in 1983?

Dr. FOEGE. Our best estimate is about $4.2 million. In 1982, we spent about $2 million, and we used funds from around CDC to do that. In 1983, it will be about $2 million over the actual appropriation. So about $4.2 million.

TUBERCULOSIS INCIDENCE

Senator HATFIELD. I have a number of questions here which I will submit for the record and ask your response to them.

You mentioned in the charts a while ago about tuberculosis. How many States are reporting increases in the incidence of tuberclosis? Can you pinpoint that pretty well in States, State by State?

Dr. FOEGE. Yes; I can provide you with reported cases in 1980, 1981, 1982, by State.

[The information follows:]

STATES WITH INCREASES IN TUBERCULOSIS CASES: 1980–82

State	1980	1981	1982[1]	State	1980	1981	1982[1]
Alabama	X			Montana		X	X
Alaska		X	X	Nebraska	X		
Arizona				Nevada		X	X
Arkansas		X		New Hampshire		X	
California	X	X		New Jersey		X	
Colorado				New Mexico		X	
Connecticut	X			New York	X		X
Delaware	X			North Carolina	X		
District of Columbia	X		X	North Dakota	X		
Florida	X			Ohio			
Georgia		X		Oklahoma		X	
Hawaii		X	X	Oregon	X		
Idaho	X		X	Pennsylvania		X	X
Illinois		X	X	Rhode Island			
Indiana			X	South Carolina	X	X	
Iowa	X			South Dakota		X	
Kansas	X	X		Tennessee	X		
Kentucky		X	X	Texas			
Louisiana				Utah	X	X	
Maine	X		X	Vermont		X	
Maryland		X		Virginia		X	
Massachusetts		X		Washington	X		
Michigan	X			West Virginia			
Minnesota	X			Wisconsin	X		X
Mississippi				Wyoming	X		
Missouri							

X = Increases.
[1] Provisional data for 1982.

CATEGORICAL GRANTS

Dr. FOEGE. Last year, the total was 25,700 which is 5 percent lower than the lowest we have ever recorded. But some States did have increases, oftentimes related to refugee populations coming into the State.

Senator HATFIELD. Again, let me ask the question as it moves from a categorical to block or back to categorical grant, do you consider there are sufficient funds within the block grant program to handle this or should funds be granted from a categorical grant program?

Dr. FOEGE. Tuberculosis is somewhat different than some of the diseases in the sense that this is a spotty problem. Across the Southern part of the United States, there tends to be more. And in the inner-city areas, so one needs the maximum flexibility to be able to put resources to a particular problem. It depends on what kind of priority a State puts on this whether they will use block grants for that.

I have a hard time answering that. In some areas, I think they are probably truly overwhelmed by the amount of tuberculosis. This is a disease where we have the technical ability to control it. It is not one that should be getting out of control.

Mr. ITTEILAG. Senator, could I add that in the budget for our refugee programs, we have a preventive health component which includes a sizable amount of money for tuberculosis control.

Senator HATFIELD. Categorical program?

Mr. ITTEILAG. Yes, sir. That is a categorical program.

I believe we have—I could put the correct amount in the record—several million dollars devoted to that.

Senator HATFIELD. All right, I would be interested in that figure.

Mr. ITTEILAG. We will insert the correct amount.

[The information follows:]

TB OUTREACH AND CONTROL

The 1984 budget request of $8.4 million for the refugee preventive health program includes an increase over 1983 of $2.8 million for refugee health assessment activities, which may be used by the States for tuberculosis outreach and control services.

Senator HATFIELD. Could you also go back to that? Let me go back to make a little amendment to the previous request that I made of you relating to the funds that you had requested as contrasted to the funds that are now before the committee.

Would it be an insurmountable task to give the committee a total figure and categorically spread or topically, however you do it, on what you made as initial requests through the OMB process, the budget requests, and what we are now looking at for all these programs? Would that be——

Mr. ITTEILAG. Yes, sir; that is entirely possible.

Senator HATFIELD. I don't want to put you to a lot of trouble.

Mr. ITTEILAG. We have the figures, and it is customary to provide them when they are specifically requested by the Congress.

[The information follows:]

CENTERS FOR DISEASE CONTROL HISTORY OF FISCAL YEAR 1984 BUDGET REQUEST

[In thousands of dollars]

	Fiscal year 1984—			Difference OMB request/ President's budget
	OPDIV request	OMB request	President's budget	
Centers for Disease Control:				
Preventive health block grant:				
Grants	.....	86,088	.....	-86,088
Program support	3,000	1,095	.....	-1,095
Subtotal, preventive block grant	3,000	87,183	.....	-87,183
Venereal diseases:				
Grants	50,000	50,000	40,510	-9,490
Program operations	6,239	6,255	7,968	+1,713
Subtotal, venereal diseases	56,239	56,255	48,478	-7,777

CENTERS FOR DISEASE CONTROL HISTORY OF FISCAL YEAR 1984 BUDGET REQUEST—Continued

[In thousands of dollars]

	Fiscal year 1984—			Difference OMB request/ President's budget
	OPDIV request	OMB request	President's budget	
Centers for Disease Control—Continued				
Immunization:				
Grants	29,305	30,482	30,482	
Program operations	15,376	15,388	11,407	-3,981
Subtotal, immunization	44,681	45,870	41,889	-3,981
Infectious disease	28,742	34,603	34,417	-186
Chronic and environmental disease prevention	25,657	26,426	24,305	-2,121
Occupational safety and health:				
Research	54,587	53,262	52,288	-974
Training				
Scientific and technical services	2,000	2,327	2,332	+5
Subtotal, OSH	56,587	55,589	54,620	-969
Epidemic services	51,538	46,402	46,030	-372
Buildings and facilities	17,840	20,440	17,370	-3,070
Program management	2,895	2,903	2,914	+11
Total	287,179	375,671	270,023	-105,648
Superfund allocation from EPA (nonadd)	(6,415)	(4,188)	(1,905)	(-2,283)
Total, Centers for Disease Control	287,179	375,671	270,023	-105,648
Outlays	261,432	382,529	269,630	-62,899
Less prior year budget authority				
Adjusted, Centers for Disease Control	(287,179)	(375,671)	(270,023)	(-105,648)
Outlays	(261,432)	(332,529)	(269,630)	(-62,899)

ENVIRONMENTAL THREATS

Senator HATFIELD. I have often said if we just had the Pentagon's petty cash funds for erasers and paperclips to give to this Center, we would probably do more to strengthen America than a lot of the things we are doing over there.

But that is personal.

Dr. Foege, what is the involvement of any of the Centers for Disease Control with regard to protecting the public against the probability of injuries resulting from chemical, biological, or nuclear terrorism?

Dr. FOEGE. We do maintain activities looking at the risk and threats, particularly of biological and chemical agents. And, indeed, one part of the budget we have submitted includes some work with Los Alamos that I think may be one of the most exciting projects that we have undertaken.

Ordinarily, to diagnose a biological agent, one does cultures in the lab. It may take hours to days to get a result. In fact, something like tuberculosis actually takes weeks to grow out. Each organism has to be different, obviously, or it wouldn't be a different organism. And the difference is coded in DNA and RNA fractions.

We have gone to Los Alamos and have found that their technology is such that it may be possible to put together in series a few things such as a cell sorter, a polarized light source that provides a beam that is diverted by the kind of DNA, RNA, hook that up to a computer, and be able to tell instantaneously what kind of an organism we are dealing with.

This obviously has implications for biological terrorism, but it has even more implications for just the practice of medicine. For instance, a pediatrician may be able to take spinal fluid from a child with meningitis, put it in a test tube, which is put into a machine, then hook up to a national data bank computer, and within seconds know that they are dealing with Haemophilus influenza, for instance, and not have to go through the long process of a culture—there are real and practical implications there.

We think some of the same opportunities exist in the chemical area—instantaneous diagnosis. We believe this may provide a quantum leap in our ability to diagnose organisms. That is part of our defense, but we also have other systems to try to evaluate. For instance, we must know how real the threat is. And, in one sense, our daily work is involved in looking at an outbreak and trying to determine is this nature or is there some other reason why we have this outbreak.

In that sense, our whole budget is aimed at that kind of defense.

NUCLEAR THREATS

Senator HATFIELD. Primarily in the biological and chemical; what about the nuclear?

Dr. FOEGE. In the nuclear area, the Department of Energy has a well-developed system for responding to those kinds of threats. We have dealt with them; in fact, we pattern much of our biological, chemical system on theirs. So that we are in contact with them, but we do not run that part of the program.

Mr. BLOOM. They operate out of Las Vegas, Nev. That is where the central response headquarters is. We visited there when working on our threat assessment system.

NIOSH RESEARCH

Senator HATFIELD. There is quite an aberration here in your request for NIOSH's research between 1983 and 1984. Would you explain that to me?

Dr. FOEGE. I wonder if I could call on Dr. Millar.

Senator HATFIELD. Sure. Dr. Millar?

Dr. MILLAR. Would you be more specific about the aberration? It seems to us a rather small and gradual increase.

Senator HATFIELD. Well, it seems to me that the inconsistency of—maybe it is because you have asked for so little.

Dr. MILLAR. Well, the request that we have made is in our extramural grant area where we have a substantial backlog of what are considered to be very good research grant proposals. The history of the

field, I think, in the past few years has been one of rather significant expansion, more scientists becoming interested in working in this field. And we have both an increase in the sort of general grants and also we announced last year a particular program for small grants aimed principally at young investigators in the neighborhood of $10,000, $15,000, $20,000, to enable them to do small projects. And we have had a very, very brisk response to that intention.

But the request we have made here will enable us, I think, to provide a continued stimulus to the academic community.

Senator HATFIELD. Changing basically the program, more specifically, what I had reference to is from 1982 to 1983. It had an appearance of a reduction. Then, from 1983 to 1984, you are back up by about the same amount that you had proposed in the last of $3 point some million from 1982 to 1983. And then 1983 to 1984 is about a $4 million increase.

So you had a decrease, then an increase.

Dr. MILLAR. Well, I am not sure I follow the figures. The figures that I am familiar with are an increase of $1.5 million requested for this year in our extramural program and a stable funding level in the intramural program.

Senator HATFIELD. You go from $51.8 million budget in 1982 down to a $48.3 million in 1983. And then from 1983 to 1984, we are looking at a $4 million increase.

Mr. BLOOM. There was a program decrease from 1982 to 1983 of around $5 million in occupational safety and health research, primarily in our in-house activities. The program increases in 1983 are limited to the small extramural research grant program that we have.

There were some builtin increases that also could make it appear there is a larger jump back.

Offsetting that, though, is a decrease of nearly $6 million in the educational resource centers and other training grants of the Institute.

NIOSH TRAINING

Senator HATFIELD. OK, in the NIOSH training program, we are looking now evidently at the sources of funding to support these occupational safety and health training activities, which have been supported up to now by the Federal Government.

Do you feel that there are realistic possibilities of getting these substituted funds from such other sources?

Dr. MILLAR. The programs themselves now are funded from other sources to the tune of about 25 percent or so of the total. And in view of the fact that these centers do serve basically corporate and organized labor organizations, there should be opportunities for increased funding out there.

I don't think the response to date has indicated that there is any great eagerness on the part of corporate American or organized labor to assume these costs. But I think that certainly our position is that other funding sources should be sought for what was initiated as basically a pilot type of activity.

Senator HATFIELD. I believe in a previous hearing that there was a reference made to requests that had been sent out to about 55 corporations for such contributions, and they were 100 percent negative in response. And some of the States who have provided some funds have also indicated in the meantime that they plan to reduce those funds that have been previously given by States.

Now, in the light of that record, do you really believe that you are going to find the supplemental funding from these sources?

Dr. MILLAR. I think it is going to be a real challenge for the universities involved.

Senator HATFIELD. Another way of saying you are hedging your bets at this point.

Dr. MILLAR. I would like to mention, of course, that in addition to the ERC program which is the big and most visible element of the training activity, there is also a smaller activity that involved what we call special grants to other universities, not involved in the educational resource center program.

That is a small program, but it does represent an area of some flexibility for us in identifying those institutions who are just beginning to develop interests in occupational safety and health. So we think that is an important activity.

Senator HATFIELD. Dr. Dowdle, do you have any comments you wish to make on any subject we have covered or not covered?

Dr. DOWDLE. Thank you very much. It is very difficult to add to Dr. Foege's statement.

Thank you.

Senator HATFIELD. Mr. Bloom?

Mr. BLOOM. No.

DR. FOEGE'S LEADERSHIP

Senator HATFIELD. Dr. Millar, any further comments?

Dr. MILLAR. Yes, sir. I would like to say that all of us at CDC are very sad at Dr. Foege's news. I think you can see from this morning's session the sort of leadership and imagination and dynamics that he has brought to us over a period of years. I am going to be sorry to see him go.

Senator HATFIELD. So say we all.

There is no way of having you reconsider in light of all these testimonies? All the arguments you gave to me or all the reasons prior to the meeting are the very reasons that would say to me why should I run for another term next year. It puts really a heavy damper on that logic.

You say 5 years; this has been 16 for me, 32 in public life. Isn't that about enough?

Dr. FOEGE. No.

Statement of William H. Foege

I am appearing before you to support the budget request for fiscal year 1984 for the Disease Control Appropriation, formerly the Preventive Health Services Appropriation. This fund provides the principal source of support for the Centers for Disease Control (CDC). Our mission is to prevent unnecessary illness and suffering and premature death. In striving to attain this goal, we are guided by the 1990 Health Objectives for the Nation.

1990 OBJECTIVES

The 1990 Objectives for the Nation were established in 1980, as the result of a year long effort involving more than 500 individuals and organizations from both the private and governmental sectors. These objectives have proven to be an extremely useful device for concentrating the efforts of the various parts of the health community on determining steps that need to be taken toward these individual goals. In September 1982, we had a meeting to assess progress to determine whether any "mid-course" corrections were needed. I am especially pleased with the progress in a few areas: The infant mortality objective is to reduce the number of deaths per 1,000 live births from 13.8 in 1978 to 9 by 1990. For 1982, the rate was 11.2; we are more than halfway there. For childhood immunizations, we established that, by 1990, 90 percent of all children should be immunized against measles, mumps, rubella, polio, diphtheria, tetanus, and polio by age 2. We have exceeded that level for children entering school and are now concentrating on means of achieving early immunization of preschoolers. California and Utah are establishing State objectives based on 1990 Objectives for the Nation, and the Model Standards for Community Preventive Health Services.

With this as background, I would like to devote the rest of my statement to highlights of our program and the budget request that is before you.

IMMUNIZATION

The Childhood Immunization Initiative continues to be a successful program and an outstanding example of what can be accomplished through the concentrated and cooperative efforts of public, private, and voluntary workers at all levels: National, State, and local. When the measles vaccine was licensed in 1963, there were reported nearly 270 cases per 100,000 population, and now the rate per 100,000 is so low it does not even show on the chart. There has been some concern that recent outbreaks among college students may be an indication of a breakdown in our program. To the contrary, it is a sign of the success of our recent intense efforts to immunize school age and preschool age children. What we are seeing is the introduction of measles infection among groups of susceptibles who were missed in the early years after licensure of the vaccine and who are concentrated on

CHART 1

college campuses. The Public Health Service, acting on the advice of the Advisory Committee on Immunization Practices has recommended that colleges and universities establish immunization requirements for college enterers.

VENEREAL DISEASES

In our fight against the sexually transmitted diseases we face formidable obstacles. The diseases are relatively easily transmitted; infection usually confers little or no natural immunity; and we have no vaccine. To control syphilis and gonorrhea, for instance, we must find and bring to treatment people who have contracted the diseases and then prophylactically treat their contacts to break the chain of transmission. The difficulty of this task is compounded by two factors: (1) In recent years, there has been an increase in sexual activity because we have a larger, sexually active population and mores have changed; and (2) despite these changes, we are still dealing with an aspect of life that is considered both private and sensitive. In the face of these difficulties we are making progress. We have turned around the gonorrhea epidemic which peaked in 1975 when the age-adjusted gonorrhea case rates rose to nearly 450 per 100,000 population. We have reduced this to less than 390--a decrease of 14 percent by the end of 1982. Also, between 1973 and 1981, the number of visits by women to physicians' offices for pelvic infections fell by a dramatic 45 percent.

CHART 2

INFECTIOUS DISEASES

The infectious disease part of our budget covers a wide range of activities and diseases, including acute illness such as influenza, and chronic infections like tuberculosis. The infectious diseases have not been conquered. As a group they represent well in excess of 100 million episodes of illness and more than 100,000 deaths in this country each year. In CDC, you have an invaluable national health resource. We strive to maintain the needed expertise and capability to deal with both the common and the uncommon infectious diseases. We have assembled a depth of capability that we cannot expect each State to build. I will concentrate my remarks in the following areas:

Acquired Immune Deficiency Syndrome (AIDS). Last year, I reported on a newly emerging, serious health problem--the occurrence of Kaposi's Sarcoma and opportunistic infections in young men. Our early concerns have been confirmed and the problem which we now call Acquired Immune Deficiency Syndrome continues to grow. With the resources that Congress has made available, we have been able to maintain our special efforts to identify the cause of the disease and the populations at risk. As of last week there were 1300 reported cases and 489 deaths attributed to AIDS. The disease is showing up especially among sexually active homosexual males, intravenous drug users, and Haitians. In addition, we have found cases among hemophiliacs, heterosexual partners of AIDS patients, recipients of blood

CHART 3

transfusions, and children of parents with AIDS. I have converted the task force that I established last year into an operational unit in our Center for Infectious Diseases. We are conducting laboratory studies in an effort to discover an etiologic agent; we are conducting epidemiologic studies to learn more about the disease as it occurs in our population; and we are establishing special surveillance activities in three major metropolitan areas that have been reporting the highest number of cases. Although indications are that AIDS is caused by an infectious agent and we are concentrating our efforts in that direction, we are not ignoring the possibility of chemical causes. For instance, in a study done by our National Institute for Occupational Safety and Health (NIOSH), we have been able to determine that nitrites, an early chemical suspect, are not the causative agent.

Strengthening the science and technology base. In our 1984 budget, we are seeking resources to strengthen our science and technology in two ways. The first would provide funds and positions needed to speed up both our knowledge and application of the molecular biology technology. From this we will gain new tools and better materials for research, for diagnosis, and for the development of drugs and vaccines. Also, we are seeking funds to upgrade our scientific equipment. We need to replace old, out of date, or worn out equipment and if we are to continue to provide scientific expertise in disease control, we must acquire modern equipment. In addition to increasing our effectiveness or improving our efficiency, we have reached the point where we need state-of-the-art equipment if we are going to be able to keep our competent scientists.

CHRONIC AND ENVIRONMENTAL DISEASE PREVENTION

Core Program. Through a staff of physicians, scientists, and other health professionals, CDC carries out numerous responsibilities and program activities related to environmental health and chronic diseases. CDC is responsible for the management of PHS response to environmental emergencies; maintaining a comprehensive focus on the evaluation of human exposures to toxic substances; maintaining surveillance and carrying out epidemiologic investigations of birth defects; and working with States in the surveillance and study of nutritional status. We conduct research and evaluation and provide national leadership in the implementation of health education and health promotion programs, and in the development of effective strategies for preventing complications of diabetes.

Our efforts have led to expanded responsibilities in two areas that deserve special note, which require interagency cooperation--Superfund activities and the Agent Orange/Vietnam experience studies.

Superfund. CDC has been designated the responsibility for coordinating the HHS responsibilities under the

Comprehensive Environmental Response, Compensation, and Liability Act, referred to as the Superfund. Building on the core staff of our Center for Environmental Health, we have established a Superfund organization from which we are coordinating CDC efforts and those of other parts of the Public Health Service. These activities are being funded under an interagency agreement with the Environmental Protection Agency. In the past year, we have provided approximately 175 health consultations regarding health issues at Superfund sites and have assisted in 27 emergency responses. Currently, we have a major effort underway in Missouri concerning dioxin exposure of individuals living or working in and near Times Beach and other sites in the State. CHART 4

Agent Orange/Vietnam Experience Study. Under an interagency agreement with the Veterans Administration, we are in the process of developing a protocol for a study of the health status of veterans, including possible health effects of exposures to the herbicide Agent Orange, during their experience in the Vietman conflict. The study we are proposing is among the largest epidemiologic studies ever designed and will take 5 years to complete.

OCCUPATIONAL SAFETY AND HEALTH

Building on the strengths of NIOSH, a special emphasis has been given in the past year to sharpening our efforts to prevent illness and eliminate hazards in the workplace.

The 10 leading occupational health problems. To better direct the work of the Institute, NIOSH senior scientists have compiled a list of the 10 leading causes of work related illnesses or injuries. It is hoped that beyond providing guideposts for NIOSH operations, the process of defining the leading work related health problems can result in setting national priorities and objectives for occupational health, which will serve to galvanize the combined efforts of Government, Labor, and Industry. CHART 5

Improving the quality of research. After a careful review of NIOSH research, the Institute's scientists and their work generally deserve high marks. What has been lacking are the institutional processes practiced in the research community to assure scientific credibility. To this end, the Institute has strengthened its peer review requirements and we have established a Board of Scientific Counselors to serve as an independent scientific panel to review NIOSH directions and programs. Toward the goal of strengthening investigator-initiated research, we are requesting increased funding for occupational safety and health research grants.

EPIDEMIC SERVICES

CDC maintains surveillance of diseases, provides reference diagnostic services to State health departments, carries out the quarantine responsibilities for the Nation, and provides epidemic assistance and investigation of

disease outbreaks and other health emergencies. For example, we assisted Alaskan health officials in the investigation of botulism in Eskimos; we investigated toxoplasmosis in Florida; cholera in the Truk Islands; the health effects of volcano emissions in Hawaii; and were called in by the Canadian Government to assist in the investigation of infant deaths in a Toronto hospital. In our budget request we are seeking to further improve our capabilities.

Rapid detection and response capability. We believe that it is time to apply space age technology to finding solutions to the time consuming and laborious problems that often confront us when we attempt to respond rapidly to health emergencies. Based on our review of technology developed in Los Alamos, we believe that we can combine our knowledge of biological agents and chemical properties with computer and laser capabilities to develop procedures for rapid and reliable detection of microorganisms and toxic chemicals in field and clinical settings. Coupled with this technology improvement, we propose to increase the strength of our Epidemic Intelligence Service.

Strengthening the application of prevention research. We are proposing to initiate a modest prevention development and demonstration program that will permit us to extend our own capabilities. We will be able to support a few projects such as the demonstration of effective health promotion or risk reduction intervention, the study of drug resistant diseases, and the demonstration of childhood injury control measures.

State-of-the-art equipment. In programs funded in this activity, as in the infectious disease activity, we need to replace old equipment and to acquire new and improved instrumentation that can extend the effectiveness of our scientists.

New Virology Building

Since submitting the 1984 budget, the funds we were seeking to construct a new high containment laboratory in Atlanta have been made available through the recently enacted "jobs bill." Clearly, we need additional facilities for handling deadly viruses. In 1950 when our Clifton Road laboratories were designed, there were only 20 viruses and rickettsia in the most dangerous classifications (Class 3 and Class 4) that required containment conditions for safe handling. Today there are 79. With our present facilities, we can only work on two Class 4 viruses at one time. Thus, we have to limit our continuing laboratory investigations in order to be prepared to handle emergencies that may arise. It must be remembered that we have the only civilian diagnostic laboratory in the Nation capable of safely handling the entire spectrum of highly hazardous diseases.

CHART 6

Other Budget Changes

For 1984, the Preventive Health Services Block Grant has been consolidated with other health block grants in an appropriation to be administered by the Assistant Secretary for Health. There are budget reductions involving Tuberculosis Control, Fluoridation, and Childhood Lead Poisoning that are being proposed on the basis that programs of this nature should be assumed by the States in accordance with their priorities for use of block grant funds. Also, no funds are being requested for occupational safety and health training.

I will be happy to answer any questions that you may have.

Chart 1

MEASLES MORBIDITY

PER 100,000 POPULATION

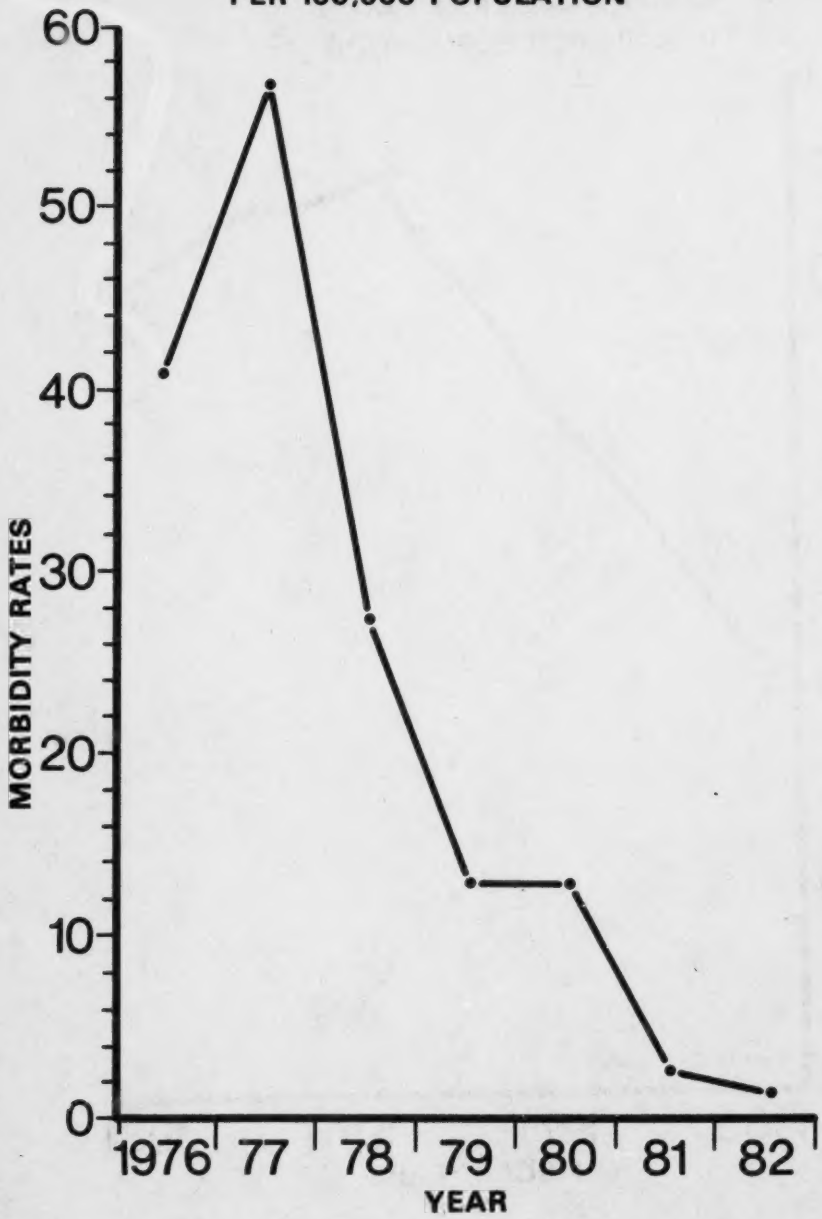


Chart 2

AGE-ADJUSTED GONORRHEA

PER 100,000 POPULATION

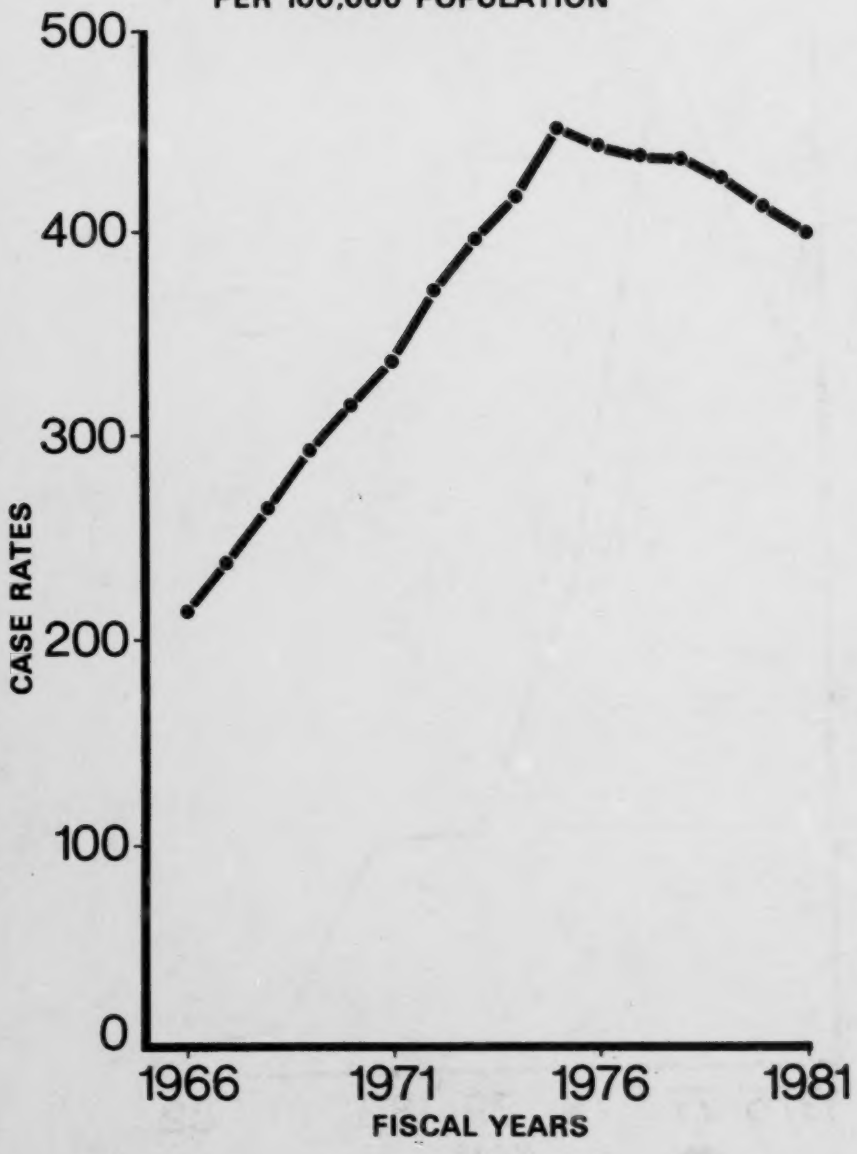


Chart 3

AIDS INCIDENCE

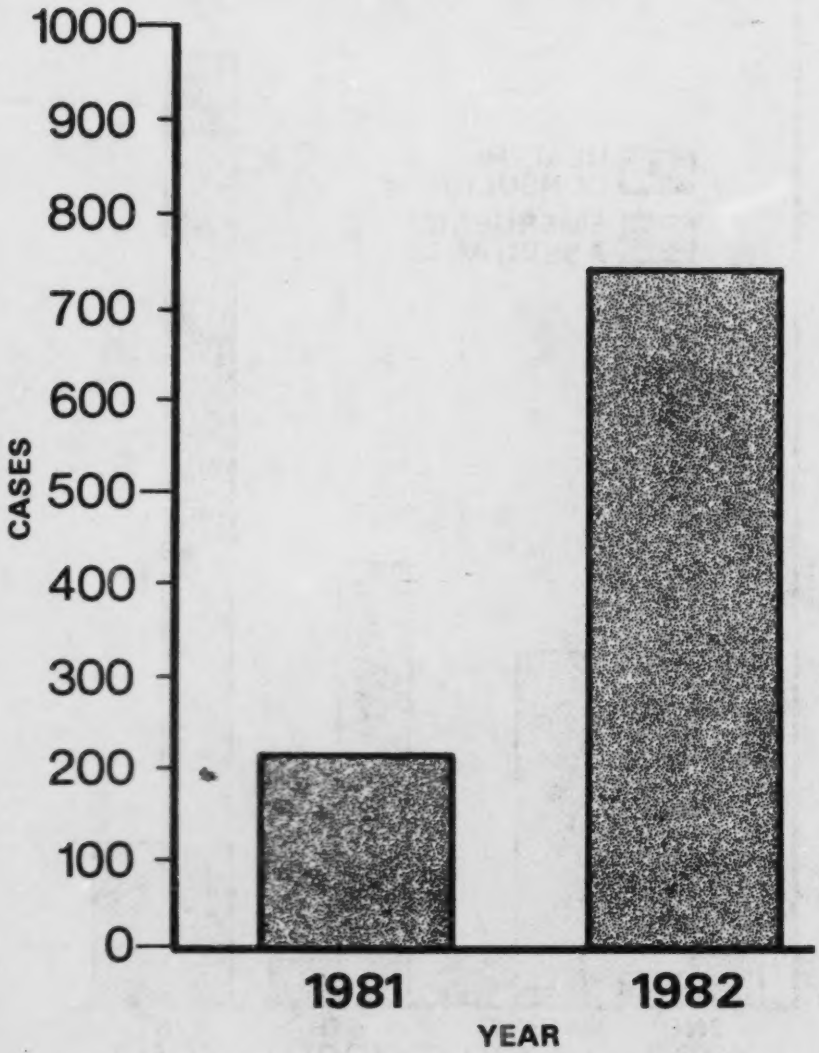


Chart 4

SUPERFUND ASSISTANCE

CONSULTATIONS/EMERGENCIES

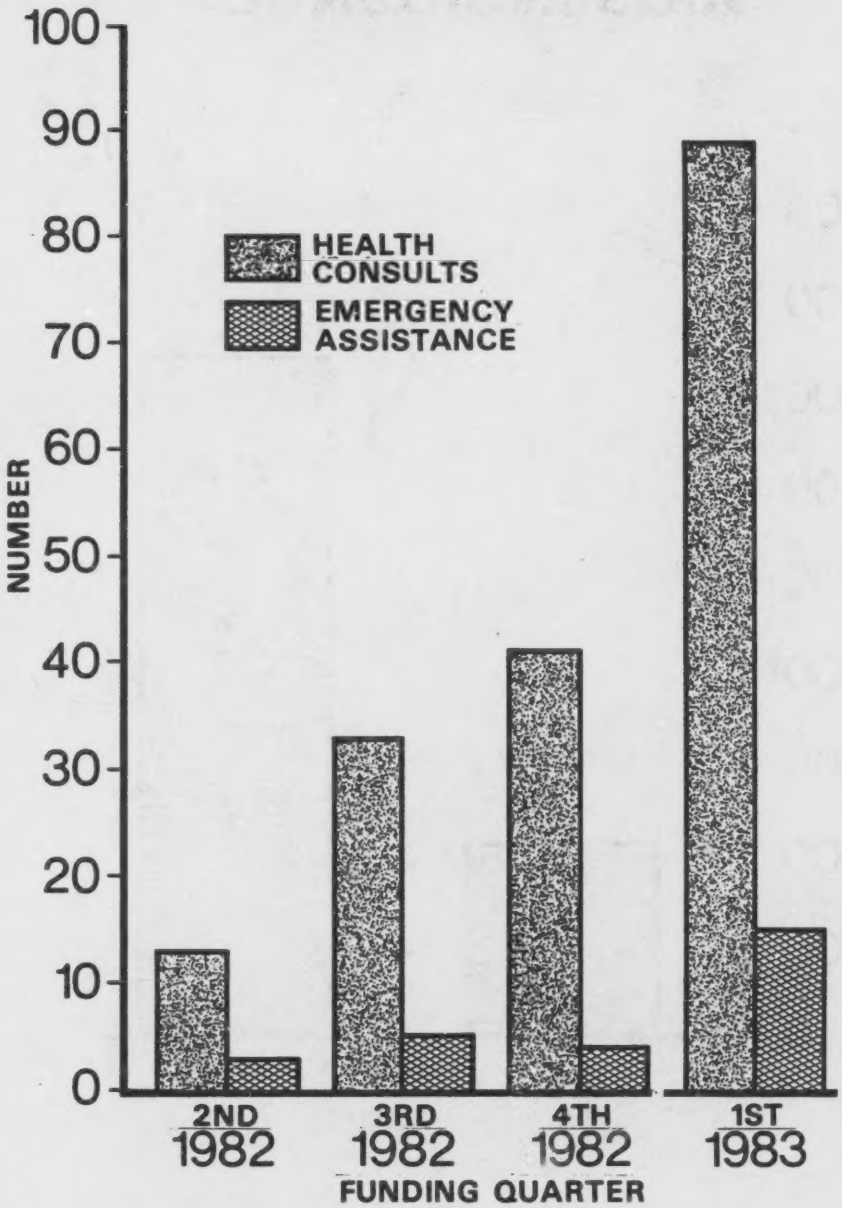


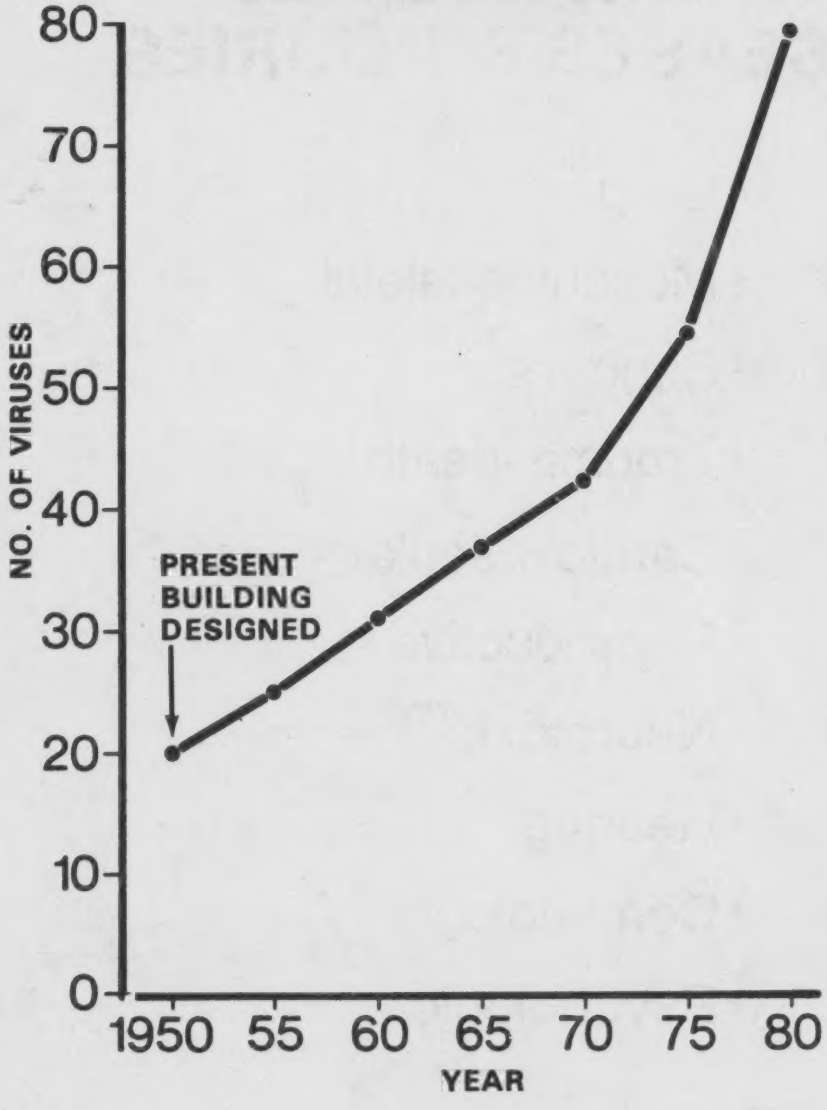
Chart 5

TEN LEADING WORK-RELATED DISEASES & INJURIES

- Lung
- Musculoskeletal
- Cancers
- Trauma, death
- Cardiovascular
- Reproductive
- Neurotoxic
- Hearing
- Dermatologic
- Psychologic

Chart 6

VIRUSES REQUIRING SPECIAL CONTAINMENT PROCEDURES



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Biography of William H. Foege

NAME	:	William H. Foege, M.D.
POSITION	:	Director, Centers for Disease Control
BIRTHPLACE AND DATE	:	Decorah, Iowa, March 12, 1936
EDUCATION	:	Pacific Lutheran University, 1957, B.A.
		University of Washington Medical School, 1961, M.D.
		Harvard University, 1965, M.P.H.
EXPERIENCE		
1977-Present	:	Director, Centers for Disease Control, Atlanta, Georgia
1976-1977	:	Assistant Director for Operations, Center for Disease Control
1975-1976	:	Assistant to the Director, Center for Disease Control
1973-1975	:	Medical Officer, World Health Organization, New Delhi, India
1970-1973	:	Director, Smallpox Eradication Program, Center for Disease Control
1969-1970	:	Chief, International Branch, Smallpox Eradication Program, National Communicable Disease Conter
1968-1969	:	Chief of Operations Area B, Nigeria, Dahomey, Togo, and Ghana, Smallpox Eradication/Measles Control Program, National Communicable Disease Center
1966-1967	:	Epidemiologist, Smallpox Eradication/Measles Control Program, Eastern Nigeria
1965-1966	:	Medical Officer, Immanuel Medical Center, Yahe, Eastern Nigeria
1962-1964	:	Epidemic Intelligence Service, Communicable Disease Center
1961-1962	:	Intern, USPHS Hospital, Staten Island, New York
1967-1976	:	World Health Organization Consultant
TEACHING APPOINTMENTS	:	Visiting Lecturer on Tropical Public Health in the School of Public Health, Harvard Medical School, Boston, Massachusetts
		Clinical Professor, School of Medicine, Emory University, Atlanta, Georgia

ASSOCIATION MEMBERSHIP :

American Epidemiology Society

American Public Health Association

American College of Preventive Medicine

American Medical Association

American Association for the Advancement of Science

Royal Society of Tropical Medicine and Hygiene

Indian Society for Malaria and Other Communicable Diseases

HONORS :

Honorary Doctor of Science, Tulane University, 1980

Recipient of the University of Washington School of Medicine Distinguished Alumnus Award, 1979

Honorary Doctor of Laws, Valparaiso University, 1978

Recipient of the 1978 Joseph C. Wilson Award for achievement and promise in international affairs

Honorary Doctro of Science, California Lutheran College, 1977

Recipient of the Pacific Lutheran University's Distinguished Alumnus Award, 1976

CDC Special Achievement Award, March 1975

PHS Superior Service Award, May 1970

Delta Omega, 1965

Honorary Doctor of Science, Wartburg College, 1979

CLOSING REMARKS

Senator HATFIELD. Thank you, gentlemen, it has all been a very enlightening experience, as it always is for me.

I feel so different in having testimony like this, the joy you experience, seeing the direct achievement and the sadness you feel about how much more we have to do and perhaps how inadequate the funding and other resources are that we have to work with at the moment; lack of priority that unfortunately so much is placed upon this kind of program.

I know no program that demonstrates more eloquently that Government has compassion, and Government can care. That affects in so many ways, people's attitude toward their Government when they have so many frustrations about the bigness of Government, the feeling of indifference and impersonality of Government, the lack of trust that rests between Government and the people themselves.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

So you are doing far more than medical research or health research. I think you really demonstrate again the human dimension of Government in action.

I want to thank you for it. The questions referred to earlier will be inserted in the record.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

Questions Submitted by the Subcommittee

PREVENTIVE HEALTH SERVICE BLOCK GRANT

Question: The FY 1983 Senate Report (97-680) expressed the Committee's view that there is a need for better information about the uses of the block grant funds and encouraged the Department to work with the States in developing a more uniform, national data system on the block grants. In your FY 1984 budget documents you indicate that sources already exist to provide information on the uses of these funds. What specific sources now exist which provide us with information as to States' uses of the Preventive Health Services Block Grant Funds?

Answer: The legislation establishing the Preventive Health and Health Service Block Grant requires annual reports from the States on the use of the funds provided. These reports are now coming in to the Department. The applications from the States also provide information on the proposed use of funds, and progress reports on past activities. A report will be prepared for the Congress by October 1, using these documents as the primary source of information.

Question: How are the States spending these funds? What trends can be noted about the ways funds are being spent?

Answer: A review of the 1983 applications indicates that the States have not dramatically changed their areas of program support because of the transition to block grants. Most of the categorial programs were awarded to States, as are the block grants, so it is not surprising that minimal changes have occurred. The reductions in funding tend to be applied on a prorata basis across programs.

Question: What specific formerly categorial activities, now included in the block grant, are not being funded?

Answer: There is no clear trend across all States, but it appears that Fluoridation efforts and Emergency Medical Services are more frequently reduced in funding from the categorical levels. Even in those programs, however, most States maintain efforts in these programs, i.e., Fluoridation 32 States, Emergency Medical Service 39 States.

Question: Which activities tend to be of the highest priority?

Answer: Health Education programs and Hypertension Control efforts are being supported in 48 project areas. Service to Rape victims (an "earmarked" program) are being provided in 47 project areas.

Question: Which States are taking advantage of the provision in the law for them to transfer funds from the Preventive Health Block Grant to other health programs?

Answer: Only Oregon has indicated transfer of funds from their block grant to another block (Maternal and Child Health).

Question: Last year you indicated that four States were not participating in this block grant. Are all States now

assuming the administration of this block Grant? (If not, which States are not, and why?)

Answer: All States eventually participated in this Block Grant in 1982, and all continued their participation in 1983. The two Indian Tribes that are eligible for funding directly from the Department also participated both years.

RAPE PREVENTION

Question: By law, under the Preventive Health Services Block Grant, at least $3 million is required to be available to the States on the basis of population for services to rape victims and for the prevention of rape. What information do you have on the ways the funds for Rape Prevention and Services are being used?

Answer: The applications for funding describe some of the activities being supported. In addition, the compliance reviews have added to the knowledge of these programs.

Question: What specific prevention activities are being supported?

Answer: Among the items being supported are rape crisis centers and/or domestic violence shelters, telephone hot lines, education efforts (victims and services providers), and protection enhancement (laboratory, law enforcement).

FLUORIDATION

Question: Grants for the fluoridation of community water supplies were consolidated into the Preventive Health Services Block Grant. Although it was not requested by the Administration, the Congress has seen fit each year, for the past two years, to provide funds to CDC to provide direct technical assistance to the States in the area of fluoridation. Is it necessary for CDC to continue to provide direct technical assistance to the States in the area of fluoridation?

Answer: In Fiscal Years 1982 and 1983, and now for Fiscal Year 1984, the Administration has chosen not to request funds to support the technical assistance and consultative fluoridation activities at the Centers for Disease Control. The States are expected to apply the knowledge and experience gained with CDC technical and categorical financial assistance in the last few years to develop and maintain the capacity to assume responsibilities in these areas.

However, in both 1982 and 1983, the Congress restored $1.1 million in direct operating funds so that CDC could maintain a national focus for fluoridation activities. In FY 1984, we intend to continue to provide limited technical assistance and consultation when requested by States and local communities.

Question: To what extent are States using their block grant funds for fluoridation programs?

Answer: Based on a review of Block Grant applications 32 States still maintain fluoridation activities but we lack hard information about the levels of effort. Anecdotal information indicates that 6 States, and Guam have increased their fluoridation funding level; 12 States have decreased their funding level; 18 States indicate there is no fluoridation activity intended; and 12 States have not specified a funding level. We have no information regarding the remaining two States.

Question: Which States have eliminated or significantly reduced fluoridation activities as a result of funds being block granted?

Answer: Based on anecdotal information that we have received, seven States that had categorical fluoridation project grants have eliminated their fluoridation activities under the block grant: Connecticut, Minnesota, Montana, New Jersey, New York, South Dakota, and Washington. Twelve States have reduced their fluoridation funding since the advent of the block grant: Alabama, California, Colorado, Indiana, Massachusetts, Missouri, New Mexico, North Carolina, Ohio, South Carolina, Virginia, and West Virginia. Two of the States may have good reason since they have almost saturated the number of communities that need their water supplies fluoridated.

Question: If people postpone costly dental work for economic reasons, will fluoridation be of any help in slowing the development of more serious, and eventually more costly, dental conditions?

Answer: Fluoridated drinking water will not eliminate the need for dental treatment in persons who already have substantial dental problems, such as advanced periodontal disease. However, the benefits of community fluoridation in maintaining dental health are substantial. Persons drinking optimally fluoridated water from birth have teeth which are more caries-resistant. The caries rate among children drinking fluoridated water can be as much as two-thirds less than that among children drinking children's dental care in terms of both cost and treatment time. Children receiving the benefits of fluoridation require fewer treatment services and the treatment that is required is less complex and, therefore, less costly and time-consuming to provide. The cost of children's dental care in fluoridated areas can be less than one-half the cost in fluoride-deficient areas.

Extractions of permanent teeth and premature loss of primary teeth are greatly minimized, thus eliminating the necessity for such costly procedures as space maintainers and fixed and removable prostheses. Crooked and overlapping permanent teeth caused by premature loss of primary teeth can be prevented, thereby reducing the need for orthodontic therapy. Adults consuming optimally fluoridated water throughout life can expect fewer tooth extractions due to caries and are less likely to become edentulous in later life, thus reducing the necessity for full dental procedures.

BLOCK GRANT COMPLIANCE

Question: What investigations has the Department conducted on States' use of the block grant funds to evaluate their compliance with the block grant's requirements?

Answer: Reviews were made in five States in FY 1982. Reviews in ten additional States are planned for FY 1983. These investigations cover the area of funds received by the States to evaluate compliance with the requirements of the PH&HS Block Grants.

Question: Which States have been investigated?

Answer: Rhode Island, Georgia, Minnesota, New Mexico and Oregon in FY 1982, Oklahoma in FY 1983.

ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

Question: There has been a great deal in the press lately about the life-threatening condition we call AIDS--Acquired Immune Deficiency Syndrome. In both FY 1982 and FY 1983, the Congress appropriated funds to the CDC for AIDS investigations and surveillance, which the Administration had not requested. For FY 1984, however, you are requesting an appropriation of $2 million for AIDS. $2 million was specifically provided by the Congress for AIDS activities in FY 1983. How much will CDC actually spend on the study and surveillance of AIDS in FY 1983?

Answer: CDC will spend an estimated $4.2 million in FY 1983 for surveillance, epidemiologic studies, and laboratory investigations of AIDS.

Question: Since June of 1981, how many cases of AIDS have been reported?

Answer: Through April 13, 1983, one thousand three hundred and thirty-nine (1,339) AIDS cases have been reported.

Question: How many new cases are being reported each week? Where are most of the victims located?

Answer: Currently, almost five (5) cases per day or approximately 35 cases per week are reported to CDC. Over 65% of the cases have been reported from New York City, San Francisco, Los Angeles and Miami.

Question: What is the fatality rate?

Answer: Overall, the case fatality rate is 37.7%. For cases diagnosed over two years ago, the case-fatality rate is 86%.

Question: What do we know about the transmission of AIDS?

Answer: We believe that AIDS is probably transmissible sexually or through exposure to blood or blood products.

Question: How close are we to identifying the infectious agent responsible for this serious breakdown of the body's immune system?

Answer: The etiologic agent of AIDS has not yet been found. However, the epidemiologic studies suggesting AIDS may be a blood-borne disease are helping laboratory scientists to select clinical specimens which are most likely to yield such an agent.

Question: What groups are most at risk?

Answer: The groups at highest risk for developing AIDS include homosexual or bisexual men, intravenous drug users, persons of Haitian nationality, and individuals with hemophilia. Approximately 6 percent of cases are not members of these risk groups.

Question: Are you concerned about the potential spread of this condition to other groups not now at risk? If so, to which groups?

Answer: If AIDS is caused by an infectious agent, we must be concerned that the disease will occur in population groups not now at risk. Based on studies now underway, a small number of AIDS cases may have acquired the disease by having sexual contact with members of risk groups or by receiving blood donated by members of risk groups.

Question: In what ways is CDC working collaboratively with the National Institutes of Health (NIH) in the long-term study of AIDS?

Answer: CDC has communicated regularly with scientists from NIH. Both agencies have shared information and participated in joint planning sessions for AIDS. As a result of the collaboration, Public Health Service interagency recommendations on the prevention of AIDS were issued on March 4, 1983.

VENEREAL DISEASE: COST/BENEFIT RATIO

Question: For FY 1982, you estimated that approximately 6,500 cases of early syphilis and approximately 179,000 cases of gonorrhea were prevented as a result of outreach efforts. What is the estimated total savings realized as a result of these successful efforts?

Answer: As a result of the prevention of 179,000 cases of gonorrhea, an estimated 47,000 cases of pelvic inflammatory disease, 8,100 cases of infertility, and 136 cases of ectopic pregnancies were prevented in FY 1982.

-- The direct and indirect minimal costs of gonococcal pelvic inflammatory disease, infertility and ectopic pregnancy prevented by sex partner and screening activities was at least $84.0 million.

-- In addition to the cost of complications, at least $25.1 million would have been spent directly or indirectly on the uncomplicated gonorrhea infections prevented in FY 1982.

-- The total minimum savings in FY 1982 of averted cases of complicated and uncomplicated disease is estimated

to have been $109.1 million. The portion of these savings attributable to CDC expenditures is $97.8 million.

-- Additional costs in FY 1982, based on projected numbers of cases if no Federal control expenditures had existed between 1972 and 1983, would have been approximately $450 million.

No hard data exist for early acquired syphilis. However, the cost to society of 177 cases of congenital syphilis reported in FY 1982, and the estimated 28 stillbirths and perinatal births, was approximately $14.5 million. No information is currently available, however, on how many cases of congenital syphilis were averted through the syphilis control effort.

Question: What does CDC estimate as the cost-benefit ratio for expenditures relating to gonorrhea and syphilis?

Answer: No cost-benefit data is currently available for syphilis.

The Federal expenditures in FY 1982 for gonorrhea control efforts led to a savings of $97.8 million to $450 million.

-- Expenditures by CDC (both grants and direct operations) for gonorrhea control were approximately $28 million in FY 1982.

-- The associated benefit/cost ratio is approximatley 3.5 to 1.

VENEREAL DISEASE

Question: Although we are beginning to be successful in reversing the trend in cases of syphilis, gonorrhea and other such diseases, the fact is that these diseases still represent a serious problem. In addition, the situation regarding herpes worsens. Your budget for FY 1984, requests a less than 2 percent increase in funding over FY 1983. Specifically with regard to gonorrhea and syphilis, is it fair to conclude that additional funding in these areas is likely to result in greater success in treating and preventing these venereal diseases?

Answer: Gonorrhea rates tripled between 1965 and 1975. Rates began to level off after 1972 when Federal support for national gonorrhea control efforts began, and have since shown a slight, but progressive decrease. The relationship of expenditures to gonorrhea morbidity appears clear: Relatively constant expenditures in gonorrhea have been followed by a small, progressive decrease. This trend has been projected to continue at proposed funding levels, despite the increase in the population at risk through 1985.

Syphilis expenditures, however, have been far less stable. These expenditures, in 1972 dollars, have been decreasing since 1975, while morbidity, which had previously been decreasing, has been increasing since 1977. Because the amount of real dollars for STD control has decreased since 1973, continuing diversions of

resources to address the gonorrhea epidemic have steadily diminished the resources available for syphilis control efforts.

Question: By how much is the number of herpes victims increasing annually?

Answer: The precise incidence and prevalence of genital herpes are not known. However, based on survey data, we estimate that more than 250,000 new infections are acquired annually.

Question: Are we seeing any signs of hope for herpes sufferers?

Answer: Yes, there is hope for herpes sufferers. Research efforts offer promise for better therapies; efforts to prevent neonatal herpes are being refined; counselling is helping individuals put their disease in proper perspective.

Question: At present, if an individual came into a clinic with herpes, what could be done for that person?

Answer: Individuals who attend an STD clinic because of suspected herpes infection are clinically evaluated by history and physical examination. Although no treatment is currently available, those who are diagnosed as having genital herpes are counselled about their disease, prevention practices, and the risks of neonatal disease. Progressively more clinical facilities are offering culture for herpes simplex virus (HSV) as confirmation of clinical diagnoses.

Question: How much in your FY '84 budget will be directed toward herpes activities?

Answer: An estimated $1.75 million in both direct operations and grant funds will be directed toward herpes activities. CDC is collaborating with Emory University to conduct research, funded by NIH, on the epidemiology and natural history of genital herpes.

VENEREAL DISEASE - 5% PROJECTS

Question: According to the authorizing statute for the VD program, 5 percent of all funds appropriated for Venereal Disease activities must be allocated to projects in education, information, research and demonstration. This Committee has received preliminary information that considerably less than the requisite 5 percent will go toward education and other activities specified in section 318(b) of the law. Are CDC's efforts adequately fulfilling your obligation in these areas?

Answer: More than 5 percent of grant funds appropriated under Section 318 have supported education/public informational activities in all 63 project areas, the VD National Hotline, chlamydial testing capabilities in selected areas, and research activities in Columbus, Ohio and DeKalb County, Georgia. We believe that these efforts are fulfilling our obligations.

Question: How much of the $40 million appropriated in FY 1983 for VD grants have been allocated to projects in education, information, research and demonstration?

Answer: During FY 1983, we expect to spend approximately $3 million to support ongoing public information and education, research, and demonstrations. In addition, applications for new projects under Section 318(b) are due by July 1.

Question: Since some of the most tragic consequences of venereal diseases occur in infants of infected parents, how have you directed your efforts toward improving clinical services and toward educating pregnant women?

Answer: Clinicians attending STD Prevention/Training Clinics are sensitized to the complications of STDs in the pregnant patient. They receive training in performing accurate and complete assessments of patient needs and the specific considerations of therapy and followup care due to pregnancy. Clinicians are trained to properly counsel patients about the importance of medical compliance and risk reduction throughout pregnancy.

Some examples of specific operational research activities currently directed towards improved clinical services for pregnant women follow:

-- The New York City VD Program has developed an outreach initiative to deal directly with Hispanic women - a high risk group for congenital syphilis in NYC. An information sheet has been written for Hispanic patients in city clinics. A pamphlet in Spanish is being developed.

-- The State of Texas has developed a system to improve clinical services offered to pregnant women.

-- The Los Angeles VD Program has organized a task force with the objective of reducing congenital syphilis.

-- There are current research efforts to: (1) Evaluate less expensive, more immediate tests for C. trachomatis infections that would be applicable for the screening of high-risk pregnant women; (2) study the STD organisms (C. trachomatis, Group B streptococci, CMV, N. gonorrhoeae) and their relationship to pregnancy outcome; (3) conduct collaboratively with Emory University, a major trial on genital herpes (HSV) infections during pregnancy as well as pregnancy outcome; (4) assist in the development of a "labor room-immediate" test for the presence of HSV viral shedding to assist in the physician's decision to perform a Caesarean section or permit vaginal delivery; (5) provide new recommendations for newborn prophylaxis directed toward a broader coverage of organisms, e.g., C. trachomatis; (6) develop a surveillance strategy for neonatal herpes infections.

VENEREAL DISEASE - HOTLINE

Question: The VD National Hotline is funded by the CDC to provide information and referrals to callers. We have been informed that the demand on the services of the Hotline is tremendous -- many times greater than the capability of the telephone lines. What does this imply about the need for this kind of information?

Answer: The need is enormous and, may, in fact, exceed the capabilities of a single, nationwide hotline. Our experience with the National Hotline reinforces the idea that all of our educational institutions and vehicles must assume greater responsibility for informing young people about these diseases and where medical services can be obtained.

Question: What is the most frequent concern of the callers?

Answer: More than one-third of callers express concern about genital herpes. Gonorrhea and syphilis are the diseases next most commonly cited by Hotline callers. Approximately one-half of the callers are interested in information on where they can go to receive medical care.

Question: What are CDC's plans to continue or expand the services of the Hotline?

Answer: Increased demand on Hotline services has resulted in the telephone company saying they will suspend the service unless the number of lines is expanded. To comply would result in a significant increase in cost and in the number of volunteer counselors required to staff the lines. CDC has been consulting with the American Social Health Association on ways to resolve the problem. One is to determine whether the telephone company itself might be able to assist in maintaining and expanding this valuable service. Another is to explore the availability of a charitable foundation to supplement support for the Hotline. At a minimum CDC will continue to support the Hotline at the current funding level.

IMMUNIZATION VACCINE

Question: This Committee has been informed that there was a 40 percent rise in vaccine prices between 1982 and 1983. Your budget assumes that for FY 1984, the increase in vaccine prices will rise approximately 10 percent, and requests a corresponding 10 percent increase. How confident are you that the projected 10 percent increase is accurate?

Answer: For the period 1978-1981, vaccine prices increased an average of 10 percent per year, and the price increase for the contract recently negotiated for 1983 was slightly less than 10 percent. -- Dr. Brandt, the Assistant Secretary of Health, has exchanged correspondence with Mr. John Lyons, President of Merck, Sharp, & Dohme expressing our concern over the increase in vaccine prices. On March 21 of this year, Dr. Brandt and I met with Mr. Lyons to further discuss our concern. Though we have been unable to obtain any reduction in the price of vaccine, we

feel that further increases in the price of vaccine will reflect only fair increases in the cost of production.

Question: Should the costs of vaccines rise more than 10 percent, will the Administration request supplemental funding in order that there be no decline in the number of children being protected under this program?

Answer: If vaccine prices rise more than anticipated and jeopardize the number of children who can be protected, CDC will seek additional funding. However, since the source of such funding might depend on the Department's financial situation at the time, it would be premature to speculate on whether a supplemental would be requested.

Question: What percentage of immunization grants are used for the purchase of vaccine?

Answer: In 1983, 44.3 percent of immunization grant funds are being used to purchase vaccine. In 1984 it is estimated that 46.7 percent of grant funds will be required for vaccine.

Question: How many vaccine doses will Federal funds be purchasing in FY 1984?

Answer: In 1984, it is estimated that about 25 million doses of vaccine will have to be administered in the public sector. This is based on an anticipated 3.85 million live births in 1984. Also, it is projected that the public sector will again have to provide about 50 percent of the total vaccine needed. Immunization grants will support the purchase of about 12.4 million doses of public sector vaccine -- mostly polio and measles-mumps-rubella vaccines. State, local, and other Federal resources will continue to provide almost all of the DTP and TD vaccines.

IMMUNIZATION STOCKPILING

Question: In FY 1983, Congress provided sufficient funds to begin a major effort toward a long-term "stockpiling" of vaccines. What is the status of stockpiling?

Answer: The CDC is currently reviewing the protocol and preparing the request for contract for the initial phase of the stockpiling. It is anticipated that this initial phase will be completed the middle of August 1983.

Question: How important is it that we purchase large supplies of vaccine and stockpile them for future use?

Answer: We believe it is very important to stockpile vaccine and propose to establish and maintain a 6 month stockpile based on the estimated time required for new sources of vaccine to be identified and licensed, or for existing facilities to resume production after a breakdown.

Vaccine production is a very complex operation which has been tightly controlled since 1902. As a condition of product

licensure, the Food and Drug Administration's National Center for Drugs and Biologics, (NCDB) requires manufacturers to:

- Test samples from each lot of vaccines for compliance with NCDB's standards for selected product qualities, e.g., potency, sterility, and labeling, and to report all deficiencies to NCDB.

- Submit samples and data to obtain NCDB's approval to change selected aspects of vaccine production, e.g., manufacturer's methods and product labeling.

- Maintain records of clinical reports of adverse reactions to their vaccines for five years, and to give FDA inspectors access to records.

Failure by the manufacturer to meet any of the standards outlined above can result in temporary interruptions in vaccine supply lasting from a few days to several months. For example, when a lot of polio vaccine fails to meet NCDB's standards, the manufacturer must produce five consecutive lots which meet the standards before any additional vaccine is released for use in the United States.

Production line malfunctions can cause manufacturers to shut down for extended periods of time. This occurred with one of the three DTP manufacturers, when production was terminated by that manufacturer for approximately one year. This shutdown created an excessive demand on the two remaining manufacturers, and required approximately 6-8 months for them to gear their own production to meet demands.

The limited number of vaccine manufacturers in the United States--one for Measles-Mumps-Rubella, one for Polio, and three for DTP/Td--highlights the need for a vaccine stockpile in case of a complete production breakdown or destruction by natural cause of vaccine production capacity.

Question: How long can stockpile vaccines be stored safely before they lose their effectiveness?

Answer: Most vaccines manufactured in the United States have a "shelflife" of 2 years and can be stored for that period of time without losing any of their effectiveness. However, we propose that the manufacturer maintain the stockpile of vaccine in its warehouse and will constantly ship from and replenish the stockpile to ensure that "fresh" vaccines are being maintained in the stockpile. When the purchase of our stockpile is completed, manufacturers must have in inventory a minimum of 6 months supply of vaccine which will be effective for a minimum period of 12 months.

Question: Will the stockpile be located in one place or in several places throughout the country?

Answer: The manufacturer would maintain the stockpile of vaccine in its warehouse and will constantly ship from and replenish the stockpile to ensure that "fresh" vaccines are being maintained in the stockpile.

Question: What is the reason for requesting a $572,000 decrease for stockpiling efforts in FY'84?

Answer: Decisions on the 1984 budget which included $4,000,000 for the stockpile had already been completed when Congress provided the $4,572,000 to initiate the first phase of the stockpile in FY 1983.

IMMUNIZATION

Question: According to an "optional use" clause, begun in 1972, Federal funds other than immunization grant funds may be used for the purchase of vaccines. States can utilize such sources as maternal and child health and preventive health services block grant funds in this manner. To what extent are States using other than immunization grant funds for the purchase of vaccines? Please provide a breakdown of sources of Federal funds used for this purpose, for the record.

Answer: During the 5-year period FY 1978-1982, immunization grantees purchased an average of 13.3 percent of their MMR (measles, mumps, rubella), MR (measles/rubella) and single antigen measles, mumps, and rubella through the Federal consolidated "optional use" clause of the contract. In addition, 19.3 percent of oral polio vaccine (OPV) was purchased through optional use during the same 5-year period.

No data are available which identify specific Federal funding sources for the optional use purchases.

TUBERCULOSIS GRANT PROGRAM

Question: In Fiscal Year 1983, Congress provided CDC with $5 million which the Administration did not request for the tuberculosis grant program. How many States are reporting increases in the incidence of tuberculosis?

Answer: Twenty-two States reported an increase in cases in 1981 over 1980:

Alaska	Nevada
Arkansas	New Hampshire
California	New Jersey
Georgia	New Mexico
Hawaii	Oklahoma
Illinois	Pennsylvania
Kansas	South Carolina
Kentucky	South Dakota
Maryland	Utah
Massachusetts	Vermont
Montana	Virginia

Also, in 1981, 27 States and the District of Columbia showed decreases in the number of cases reported below 1980.

Data on 1982 cases are provisional and need to be verified by each State. The net change, when final data have been confirmed should not significantly affect the provisional total of

approximately 25,700 cases, which represents a reduction below the 27,373 cases reported in 1981.

Question: How are TB grant funds being utilized by the States?

Answer: CDC received $1 million late in FY 1982 for tuberculosis control, and funded cooperative agreements with health departments in 12 high-incidence metropolitan areas. The $5 million made available for FY 1983 will permit funding of approximately 40 cooperative agreements. Activities in some of the existing projects will be strengthened, and additional areas will be added. Funds are being used primarily to strengthen the ability of these areas to provide outreach, with emphasis on directly administered therapy.

Awards will be limited to support of programs in States which reported 100 or more new cases of tuberculosis for each of the years 1980 and 1981 or had an incidence rate greater for both 1980 and 1981 than the national tuberculosis incidence rate in 1981 (11.9 per 100,000 population).

Cooperative agreements may also be awarded directly to a local health agency serving a high priority urban area with a city of at least 250,000 population which reported 200 or more new cases of tuberculosis in each of the years 1980 and 1981, or had an incidence rate greater than the 1981 rate for U.S. cities over 250,000 population (24 per 100,000 population) for both 1980 and 1981.

Question: To what extent are States using block grant funds for TB activities?

Answer: The philosophy underlying block grants is to give States flexibility in deciding how to allocate the funds. Not all expenditures for tuberculosis can be readily identified as such. In some States these expenditures may come under budget categories such as "community health services," "laboratory services," "nursing," or other more general categories. However, many States are supporting tuberculosis control activities with block grant funds.

Question: Do you believe sufficient funds exist within the block grants, and other HHS programs, so that categorical TB grant funds are not needed?

Answer: The funds requested in the fiscal year 1984 CDC budget for infectious diseases are sufficient for CDC to carry out its national responsibilities in tuberculosis operational research, surveillance, and training and consultation to State and local health departments. During the budget process, the Department carefully considered options for providing tuberculosis financial assistance to State and local health departments, including the Preventive Health and Health Services Block Grant and categorical tuberculosis project grants. We believe that the Preventive Health and Health Services Block Grant is the best alternative for tuberculosis funding.

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The tuberculosis project grants are directed primarily toward intensifying public health outreach activities in high incidence areas and population groups. In fiscal year 1984, States will have an opportunity to continue some or all of these activities using the Preventive Health and Health Services Block Grant. States are in a much better position than the Federal Government to review the success of the intensified outreach activities and rank them with other health priorities. This method of funding is an appropriate, flexible mechanism, consistent with the Administration's objective of consolidating categorical health programs into block grants to be used according to individual States' priorities. In addition, the Refugee Preventive Health program includes funds which may be used by the States for TB outreach and control efforts for refugees.

TUBERCULOSIS

Question: Last year, Dr. Foege, you reported that the growing incidence of TB in this country was partly due to apathy and the fact that people believe this is a disease that has gone away, when in fact it continues to threaten our health. What role is the CDC playing to create better public awareness as to the real threat TB poses to our nation's health?

Answer: First, it is important to point out that we expect to be able to report a decrease in morbidity for 1982, based on provisional data received from the States.

Secondly, in regard to CDC's public awareness role, the CDC reports data and analysis of the nation's tuberculosis morbidity in the Morbidity and Mortality Weekly Report (MMWR) and, periodically, in widely distributed special publications. The media monitor MMWR and frequently follow up with interviews and articles relating to the reports.

CDC regularly collaborates with the American Lung Association (ALA) and the American Thoracic Society in efforts to publicize the nation's TB problem. Last year, for instance, the CDC cooperated with the ALA in conducting the Koch Centennial Symposium in Washington, D.C., which received national media coverage.

In addition, during onsite program reviews and program consultations, CDC staff work with State and local health departments to assist and encourage the public dissemination of information concerning State/local tuberculosis problems and progress toward control of the disease.

Question: What more can the Federal government do to awaken State and local health officials to the very real threat TB poses to our nation's health?

Answer: Most State and local health officials are strongly committed to the control of tuberculosis. Their efforts are complicated by the fact that large segments of the public still believe the disease has disappeared, despite the continued occurrence of over 25,000 cases annually in the United States. The CDC role should be to continue working with health departments to assist them in evaluating ongoing control

activities, in identifying and solving problems, and in modifying control strategies, where appropriate.

HEPATITIS AND AIDS

Question: I understand that the same blood elements that are suspected of causing AIDS in some hemophiliacs are also used in the development of the hepatitis vaccine. As such, is there any basis for concern that the hepatitis vaccine could pose a risk to those receiving it?

Answer: Since hepatitis B virus vaccine is made from human plasma and much of that plasma is taken from homosexual men in New York, Los Angeles, and San Francisco, there is a possibility that the "AIDS agent" could be in the starting material from which the vaccine is manufactured. However, the vaccine production process is designed to kill infectious agents. Three virus inactivation steps are included in the production process and these have been shown to inactivate not only hepatitis B virus, but also representatives from all virus groups. Thus, the hepatitis B virus vaccine should pose no risk of AIDS for those receiving it.

Question: Are you aware of any individuals or groups who have refused to receive the hepatitis vaccine because of these concerns?

Answer: Despite reassurances from the Public Health Service and other organizations, there has been reluctance to take the hepatitis B virus vaccine. The highest priority recipients of the vaccine with funds to afford it are health care workers, but most discussion and resistance has come from this group. Although not quantified, many health care workers, who are at risk of hepatitis B virus infection, are not taking the vaccine for fear of acquiring AIDS.

TECHNOLOGY IMPROVEMENT

Question: The FY 1984 budget reflects a new effort to upgrade science and technology resources and equipment. How will these efforts contribute to the prevention of unnecessary morbidity and premature mortality?

Answer: These efforts will provide new and improved technologies for use in earlier intervention strategies in the diagnosis and prevention of infectious diseases. Rapid and accurate diagnoses provide the means for applying specific therapy regimens which shorten individual patients' periods of morbidity, reduce the risk of spread of infections, and prevent premature mortality. Production of purified molecular biology products provides cloned antigenic materials to be evaluated for their potential use in development of synthetic vaccines. These new products may be more efficacious than vaccines currently used in prevention programs and provide effective vaccines for diseases not currently controlled by immunization programs.

Question: To what extent will greater efficiencies be realized as a result of the upgrading of equipment and knowledge?

Answer: Increased efficiency will be realized with equipment that is dependable, less labor intensive to operate, and which can perform specific and sensitive analyses not possible with present equipment. Moreover, many of the equipment items needed are newer electronic devices capable of performing hundreds of assays and processing the resultant data in minutes rather than days or weeks. The amount of knowledge gained will be multiplied many times; resulting in a quicker response time in dealing with life-threatening epidemics, and earlier development of control and prevention measures to reduce morbidity associated with infectious diseases.

Question: Are the new funds you are requesting for improved technologies and equipment in FY 1984 the first installment in a long-range plan to improve CDC's full capabilities in these areas? If so, what will be the total amount needed over the next few years to accomplish your goals?

Answer: The initial assessment of scientific equipment needed to replace outdated equipment and purchase state-of-the-art equipment was $7.6 million. Purchase of equipment to replace worn out or obsolete equipment requires $1.8 million; additional new equipment that would be less labor intensive and allow more efficient use of critical staff time requires $3.8 million; and equipment needed to achieve state-of-the-art capabilities requires $2.0 million. The FY 1984 request ($4.0 million) will provide funds for achieving major improvements in the scientific base. Additional needs will be examined in the context of future budget developments.

ASBESTOS IN SCHOOLS

Question: This committee is hearing from a number of school districts throughout the nation concerned about EPA requirements that schools identify asbestos hazards where they exist in the schools. Does the Centers for Disease Control plan to assist the EPA in determining when asbestos poses a safety hazard in the schools?

Answer: Although CDC has received no request from EPA for assistance in this matter, if requested, we will provide consultation and technical assistance to EPA and to State and local health departments within our available resources.

Question: Can CDC assist EPA on monitoring and reporting asbestos levels and in removing asbestos hazards in schools?

Answer: Again, within CDC's available resources, we will assist EPA if requested. However, it is our understanding that the final rule (Asbestos; Friable Asbestos-Containing Materials in Schools; Identification and Notification - 40 CPR Part 783) makes no provision for the monitoring and reporting nationally of asbestos levels. Also, under this final rule, EPA will not be removing asbestos hazards from schools, but will be available to local education departments for consultation regarding the management and abatement of areas with friable asbestos.

SUPERFUND

Question: The Centers for Disease Control is the lead agency for coordinating Department of Health and Human Services responsibilities under the Superfund and, as such, is expected to investigate sites and initiate studies to ensure that public health and worker safety are addressed. What efforts has the Centers for Disease Control made in coordinating with the Environmental Protection Agency with regard to the Superfund program to clean up toxic waste?

Answer: As the lead agency for coordinating all Health and Human Services (HHS) activities under Superfund, the Centers for Disease Control (CDC) has made a serious effort to coordinate all HHS activity with the Environmental Protection Agency (EPA). Toward that end, CDC has negotiated and signed Interagency Agreements with EPA specifying the health services that HHS will provide, and is currently in the process of negotiating a Memorandum of Understanding between the two agencies. In addition, to enhance the coordination of HHS and EPA field activities under Superfund, CDC has assigned public health advisors to EPA's regional offices.

Since March of 1982, CDC has provided 175 health consultations to EPA on toxic dumpsites, assisted in 30 emergency responses and worked with EPA on health effects studies at, for example, Times Beach, Mo., Love Canal, N.Y., and Hollywood, Tn.

Question: How much did CDC receive from the EPA for its share of the Superfund in FY '84?

Answer: The President's Budget for FY '84 allocates $1.905 million from the Superfund for the Department of Health and Human Services' activities.

Question: How much does EPA plan to allocate to CDC for Superfund activities in FY '84? (Note: Preliminary indications are that although CDC received more than $12 million from EPA for the Superfund in FY'83, EPA only plans to allocate less than $2 million in FY'84.)

Answer: The Environmental Protection Agency is expected to transfer the $1.905 million contained in its 1984 budget for Superfund to the Department. In addition, EPA has indicated that it will negotiate with HHS to allocate additional funds for site-specific activities under separate interagency agreements.

AGENT ORANGE

Question: To what extent is the Centers for Disease Control involved in researching the possible health effects of exposure to Agent Orange or the other dioxin-containing chemicals?

Answer: The Veterans Administration and the Centers for Disease Control (CDC) have entered into an Interagency Reimbursable Agreement under which CDC will carry out the epidemiological studies authorized by Public Laws 96-151 (Section 307) and 97-72. CDC proposes that two related but separate cohort studies be conducted to determine whether Vietnam-era

military veterans as a group, including those most likely to have had significant exposure to the dioxin-contaminated herbicide "Agent Orange," suffer long-term adverse health effects. As a part of this effort, CDC also proposes to conduct a case-control study to determine if Vietnam veterans are at increased risk of contracting soft tissue sarcoma or lymphoma.

In addition to these studies, CDC is currently conducting, with support from the Veterans Administration and the Department of Defense, a retrospective case-control study to determine whether Vietnam veterans may have a higher risk of producing children with birth defects.

Question: How are your studies coordinated with the research efforts of other agencies?

Answer: CDC's studies are coordinated with the research efforts of other agencies through the Agent Orange Working Group. This Interagency Working Group was established on December 11, 1979, by the then Domestic Policy Advisor to the President and expanded by the current administration to the status of a Cabinet Council. This working group was established to study the possible long-term health effects of phenoxy herbicides and contaminants, and to design a research agenda to assure that the Federal government conducts comprehensive research on the long-term health effects of these compounds in response to both scientific and policy needs.

Question: What resources will the CDC need to conduct the epidemiology study of Vietnam veterans exposed to Agent Orange planned by the Veterans Administration?

Answer: Based on the acceptance of CDC's recommended scientific approach, it is estimated that it will require 55 positions and FTE's for each of the FY's 84-87 and cost an estimated total of $72.4 million to conduct these epidemiological studies. However, final costs are subject to change depending on the recommendations of review groups and other factors which may cause delays in the starting and ending dates.

Question: How long will this study take? What will the total cost in your budget relating to this budget study?

Answer: We estimate that it will require 4 years after the development acceptance of study protocols to complete these epidemiological studies. Since these studies are being conducted under an interagency reimbursable agreement, funds, positions and FTE's to conduct these studies are to be provided from resources appropriated to the Veterans Administration.

MORBIDITY AND MORTALITY WEEKLY REPORT

Question: Last year, CDC instituted a change in the distribution of the Morbidity and Mortality Weekly Report which had been distributed free of charge. Last fall, CDC began to charge the majority of recipients of the report anywhere from $55 to $155 dollars per year, depending on where they lived and how they subscribed. How much will be saved annually by charging subscribers for the Morbidity and Mortality Weekly Report?

Answer: CDC estimates that during FY 1983, $1,475,000 would be required to continue to provide the MMWR at no cost to all previous subscribers.

Question: To what extent have the new rates for subscriptions discouraged a large number of readers from subscribing?

Answer: CDC distributes 10,750 copies of the MMWR without charge. Recipients are primarily local, State and Federal health officials.

The National Technical Information Service currently has 13,250 paid subscribers. CDC distribution prior to October 1, 1982 was 115,000.

Question: Has alternative funding from foundations for the private sector been considered?

Answer: During recent months, nongovernment organizations have contacted CDC expressing interest in publishing MMWR information in their journals. The Annals of Internal Medicine is including MMWR indexes along with the text of selected articles. The Journal of the American Medical Association will include selected articles on a weekly basis. In the February 10, 1983, issue of the New England Journal of Medicine, the Ochsner Clinic advertised a weekly subscription to the MMWR. The New England Journal of Medicine announced in their February 24 issue that they would also offer an MMWR subscription service.

We are optimistic that, as a result of arrangements such as those listed above and through the inclusion of MMWR information in electronic data bases, MMWR information will reach even more health professionals than before the publication was offered on a paid subscription basis.

NIOSH RESEARCH

Question: For FY 1983, the Administration had requested a decrease of $3.4 million for the previous year, for occupational safety and health research (from $51.8 million to $48.3 million), which the Administration juistified as necessary to phase out lesser priority research areas. The Congress agreed to your request. Now we find that the Department is requesting an increase in the NIOSH research budget of nearly $4 million for FY 1984. What is the rationale for the inconsistency in your request for NIOSH research between FY 1983 and FY 1984?

Answer: There is a $1.5 million research increase for an initiative in the occupational safety and health research grant program. This program is important in assuring that new investigators are attracted to the field of occupational safety and health to assist NIOSH in keeping up with emerging problems in this field.

Question: What priority areas will be the focus of the increases you are requesting in NIOSH research?

Answer: The $1,500,000 program increase in research grants would be directed to the following areas: respiratory disease ($400,000), occupational cancer ($400,000), reproductive problems ($400,000) and neurotoxic illnesses ($300,000).

Question: How have the leading causes of occupational illness and death changed in the past 10 years?

Answer: NIOSH has just recently defined the ten leading work-related diseases and injuries. We will have working groups of the top scientists within the Institute in each of these areas to develop a strategy/approach for prevention of these diseases and injuries. One of the methods for developing a strategy will be to look at how these problems have changed over time (i.e what new process has been introduced to cause the problem). This approach will give the Institute some insight into controlling the occupational hazard in the future. The analysis of how these problems have changed over the past ten years has yet to be done.

NUCLEAR/BIOLOGICAL/CHEMICAL THREATS

Question: Dr. Foege, what is the involvement of the Centers for Disease Control with regard to protecting the public against threats and possible injury resulting from chemical, biological or nuclear terrorism?

Answer: E.O. 11490 (which assigns emergency preparedness functions to Federal agencies) and a further delegation by the Dep[illegible]nt to CDC requires that CDC participate in the dev[illegible]ent of preparedness relative to biological and chemical hostilities. In response to this charge, CDC actively collaborates with the Department of State (Office for Combatting Terrorism) and the FBI (Domestic Terrorism Office), both of which have lead agency responsibility regarding terorism: the former for international terrorism affecting the United States and the latter for domestic terrorism.

CDC, in cooperation with other Federal agencies having applicable technical skills, has developed a rapid response capability for assessing biological or chemical threats in order to determine if those making the threat have the capacity and the will to inflict injury or death. This capability, which is "on line" 24 hours a day, 365 days a year, can provide a technical and behavioral evaluation of biological/chemical threats made by terrorists or others (such as extortionists, single issue extremists, or the insane).

The scope of cooperation with lead agencies and other Federal technical agencies also includes a capacity to work collaboratively for the purpose of preventing subnational biological/chemical hostilities from occurring, or, in the event they do occur, being able to manage the incident in a way which assures maximum protection for the health of the general population. Because the public health response to illness/death produced by biological or chemical agents is much the same regardless of cause, CDC's capabilities are as responsive to the event arising from a hostile act as to naturally occurring or accidentally caused illness and disease and thus constitute an

important capability for managing biological/chemical subnational hostilities.

CDC is also collaborating with Los Alamos National Laboratory in developing technology which would provide an almost immediate indication of the presence and identity of biological agents. This capability would be extremely useful in the event of biological subnational hostilities.

While CDC participates actively with other Federal agencies in threat evaluation and incident management activities and the development of new technology relative to subnational biological/chemical hostilities, it has no involvement with subnational hostilities involving nuclear materials or devices.

NIOSH TRAINING

Question: Once again we note that you are requesting no funds for NIOSH training activities which the Congress funded at a level of $5,760,000 in FY 1983. As part of the rationale for eliminating this activity in FY 1984, your budget states that this position is in support of the Administration's policy to reduce the Federal budget through shifting programs to the private sector.

One of the 15 educational resource centers (ERC's) supported with these funds has expressed concern to this committee over its inability to locate private sources of funding. They stated the following:

"In 1982, we approached 55 major companies requesting support for our training programs. All responses were negative . . . . Furthermore, those few state governments that have supported occupational safety and health training in the past are proposing major cuts in existing programs as they, too, struggle, to balance their budgets." My question is: How realistic is it to assume that other sources of funding will be found to support occupational safety and health training activities now supported by the Federal Government, in these troubled times?

Answer: Educational Resource Centers currently receive approximately 25% of their funding from sources other than the NIOSH federal training grant (i.e. States, private organizations). The demand for occupational safety and health professionals by the private sector is a need/demand that is driven by the legislation and regulations in this area. When the supply is not met by the demand, private entities will be forced to invest in these professions. In the meantime, the universities will have to explore expansion of alternate funding sources in order to support the ERC programs.

Question: How has CDC or the Department of Health and Human Services assisted in locating alternate sources of funding for these training activities?

Answer: When the program was first announced, funds from the Federal government were described as "seed" money to initiate programs in an effort to develop the field of occupational safety and health as a viable profession. In the original program

announcement, the Institute required that each ERC have an advisory council composed of representatives of private industry, community organizations, government and others who would be users of the ERC as a regional resource in the area of occupational safety and health. Part of the charge and responsibility of this council was to look for alternate and additional sources of funding. We attempted to prepare the ERC's at the outset for the prospect of no Federal funds past the initial five year period.

NIOSH BOARD OF SCIENTIFIC COUNSELORS

Question: Can you tell us the status of NIOSH's proposed Board of Scientific Counselors?

Answer: The Institute is currently seeking nominations to the Board. It will be composed of ten members from authorities knowledgeable in the fields of occupational medicine, occupational nursing, industrial hygiene, occuptional safety and engineering, toxicology, chemistry, safety and health education, ergonomics, epidemiology and psychology. Nominations are due by May 31, 1983.

Question: Has it been established yet?

Answer: The Board was officially established on March 1, 1983. We hope to have the members selected by the end of the summer with the first meeting to be held in the fall of this year.

Question: What is its overall purpose and objective?

Answer: The purpose of the Board of Scientific Counselors for NIOSH is to provide advice and guidance to the Director of NIOSH on NIOSH research programs. Specifically, the Board will provide oversight of the Institute's research program to ensure scientific quality, timeliness, utility and dissemination of the Institute's research results.

NIOSH MOVE TO NIH

Question: As you know, it has been suggested that NIOSH be transferred from CDC into the NIH complex, wth legislation now pending to accomplish this transfer. Does the Department have a position regarding the possible move of NIOSH from CDC to the National Insitutes of Health?

Answer: The Department, as well as the Administration, does not support the transfer of NIOSH from the Centers for Disease Control to the NIH. Due to significant differences between CDC/NIOSH and NIH in mission, orientation, operation, and constituents, the goals of NIOSH are best served by maintaining its current organizational location as part of CDC.

Question: What similarities and what differences are there between the research conducted under NIOSH in its present structure and the research being conducted at the NIH?

Answer: CDC is the principal agency of the Public Health Service concerned with the prevention of unnecessary illness and premature death. NIH, on the other hand, by stimulating and

supporting basic investigator-initiated research, works to improve human health by acquiring new scientific knowledge. NIOSH and CDC are most compatible, each with their focus on operational research, and application of existing knowledge, field investigations, technical assistance.

Although there is some similarity between the research conducted by NIOSH and NIH, there is a significant difference in focus. Occupational safety and health research as performed by NIOSH focuses heavily on identifying and characterizing workplace conditions that cause disease or injury and on recommending technologies for prevention. This requires an emphasis on subjects not generally within the purview of NIOSH (safety, mining, and engineering) and outside the mission of NIH (e.g. regulation and service). CDC has long applied environmental and engineering controls to solve problems in the areas of vector-borne diseases and injury control.

CDC and NIOSH serve a different "constituency" than NIH. NIH relates to academic institutions and other organizations involved in conducting basic medical research. CDC relates to those groups primarily concerned with applying research findings: international, national, State and local health agencies, voluntary agencies, associations, and others in the public health community applying prevention programs. The primary users of NIOSH are the occupational safety and health professionals in such settings and labor and industrial organizations.

CDC operates national surveillance systems not only for infectious diseases but also for chronic and environmental health problems through the network of State and local public health agencies. In occupational safety and health, this CDC expertise is important to assess the magnitude of health problems, monitor national trends, and conduct epidemiologic studies that will be instrumental to NIOSH in identifying effective control mechanisms. NIH is not involved in such national surveillance activities.

There are other aspects of NIOSH which would be unique in the context of NIH. It is unlikely that these activities would prove compatible with the present mission of NIH:

NIOSH is mandated to respond to requests for health hazard evaluations. This service activity brings NIOSH into daily contact, sometimes confrontational in nature, with industry. To do this work, NIOSH is authorized to use warrants and subpoenas in execution of right-of-entry and right-of-access to data. NIH neither has nor depends on field response capabilities, while CDC's expertise and success in conducting field investigations and epidemic response is well known.

NIOSH is authorized to recommend standards to the Occupational Safety and Health Administration (OSHA) and the Mine Safety and Health Administration (MSHA). This requires integration of results of NIOSH research, other research, and prudent public health concerns into major policy pronouncements. These recommendations are usually controversial because they require changes in the workplace environment and often have financial implications if implemented.

NIOSH is mandated to carry out programs to test and certify personal protective equipment. Most prominent in this is the testing and certification of respirators. NIOSH, in essence, regulates this industry and experiences the associated controversy and complaints.

BUILDINGS AND FACILITIES

Question: To what extent have attrition and program cutbacks at the National Institute for Occupational Safety and Health reduced the number of employees to a point where labs an offices are currently underutilized or vacant?

Answer: The facilities which NIOSH currently occupies are being fully utilized--utilized to capacity. In fact, at the present time, we have asked GSA for an additional 10,000 square feet of storage for respirators certified by NIOSH that we are required to retain.

Question: What provisions have been made to lease or sell unused space at facilities of CDC and NIOSH?

Answer: There have been no provisions to lease or sell space at CDC or NIOSH.

Any potentially excess space in Atlanta facilities is being utilized by the relocation of NIOSH headquarters and the CDC Phoenix activities to Atlanta.

The space being vacated by the relocation of NIOSH headquarters is under GSA lease and was subsequently assigned to other Federal agencies. The Phoenix facility will be transferred to another Federal agency, probably the Indian Health Service, when the activities relocation is completed.

NIOSH activities in Cincinnati are being consolidated at the Taft and Ridge Avenue facilities. When this is completed, the space vacated in the Federal building will be released to GSA for subsequent reassignment.

BIRTH DEFECTS AND GENETIC DISORDERS

Question: What trends in the incidence of birth defects and genetic disorders can you report from your monitoring activities under the chronic disease program?

Answer: CDC monitors the incidence of over 150 categories of birth defects. Among the most noteworthy increases in reported rates during the 1970's are those for two cardiovascular defects, ventricular septal defect and patent ductus arteriosus. These two defects more than tripled in incidence over the decade. We are continuing our efforts to determine the cause of this increase, whether it is due to an artifact or to some environmental agent. Another trend being investigated is that for renal agenesis, which showed an increased incidence of about 75% between 1970 and 1980.

Rates for the 2 serious central nervous system defects, anencephaly and spina bifida, decreased about 40% during the

decade. The cause for this decline is unknown. The incidence of Rh hemolytic disease declined 65% between 1970 and 1980. This is due to more women receiving Rh immune globulin after delivery and the tendency toward having fewer babies.

The rates for many birth defects--including hydrocephalus, cleft palate, limb reduction deformity, and Down syndrome--showed very little change during the 1970's. Among those that did change significantly, the reasons are unknown, with rare exception. Environmental agents, chance, diagnostic criteria, and reporting procedures all must be considered as possible explanations for a trend.

Question: How can the incidence of birth defects or disorders be prevented or reduced?

Answer: The incidence of birth defects or disorders can be reduced through (a) professional and public education describing the association of these conditions and their causes; (b) application of available prevention strategies, such as immunization to prevent Rubella syndrome and use of Rh immune globulin to prevent Rh hemolytic disease; (c) pre-pregnancy counseling and close medical supervision of women at increased risk of having an afflicted child, such as women with diabetes and epilepsy; and (d) application of alpha-fetoprotein, to screen for disorders.

The causes and means of preventing many serious disorders are unknown. Therefore, CDC conducts research to identify these causes and define and evaluate prevention strategies. Activities include: (a) analysis of surveillance and epidemiologic data--including data on 7,000 pregnancies with and 3,000 without birth defects; (b) epidemiologic studies of premature breast development among young girls, mental retardation, cerebral palsy, and spontaneous abortion (miscarriage); and (c) evaluation of a strategy for preventing a severe birth defect of the spine through vitamin supplementation.

NIOSH

Question: It is our understanding that some 300 research grant applications have been submitted in response to NIOSH solicitations last fall. Further, we understand that these 300 grant applications from last fall have not yet been reviewed because of the dislocations caused by the move of NIOSH from Rockville to Atlanta. When do you anticipate that these applications will receive necessary attention and review?

Answer: All grants received to date (384) have been reviewed by the Occupational Safety and Health Study Section for scientific merit and peer review. These grants represent two different grant programs. During FY 1983, a new small grant program in occupational safety and health was initiated which solicited grant applications from pre-doctoral graduate students and post-doctoral researchers. Under this program, grants of up to $15,000 per year for a two-year period could be awarded. In response to this new program, CDC received 237 grant applications and 102 have been approved. In addition, 147 applications were

received for the ongoing research grant program; of these, 55 were approved.

Question: What percentage of these 300 applications do you expect to be able to fund?

Answer: Of the 384 grant applications received and reviewed, 157 have been approved (41%). As previously planned and budgeted, 40 to 45 grants will be funded during FY 1983, or 27% of those approved and 11% of the total submitted.

Question: What have NIOSH surveys found as to the demand for trained professionals in the occupational health field -- such as occupational health nurses, physicians, industrial hygienists, safety specialists, etc.?

Answer: In 1978, a contract was awarded to determine the demand for occupational health professionals. At that time, it was estimated that there were 84,850 professionals already in the field and that by the year 1985 approximately 106,000 professionals would meet the demand.

Question: Do you believe that the Educational Resource Center program (ERC) has been cost effective?

Answer: The Educational Resource Centers have demonstrated the effectiveness of providing both full-time and continuing education training of occupational safety and health professionals, specialists and technicians as well as becoming a resource to management and labor for the region in which they are located. It is because of this success that we believe it reasonable to expect that the principal users of the individuals trained - industry and State governments - will increase their financial support to maintain these centers. Federal developmental support funds have served their purpose of stimulating and strengthening interest in occupational safety and health training.

Questions Submitted by Senator William Proximare

DIAGNOSTIC TESTS

Question: Dr. Foege, last week the General Accounting Office came out with a report that was critical of your laboratory diagnostic testing service. The report indicated that you performed tests on about 103,000 diagnostic specimens at a cost of approximately $6.1 million in fiscal year 1981. Can you give us comparable data for fiscal year 1982?

Answer: The GAO analysis did not take into account the additional provisions of subsection 3a(2) of OMB Circular A-25 covering the use of user charges which states "No charge should be made for services when the identification of the ultimate beneficiary is obscure and the service can be primarily considered as benefitting broadly the general public (e.g., licensing of new biological products).

One example serves to illustrate the distinction within OMB Circular A-25. When CDC performs diagnostic testing, using the maximum containment laboratory, for a suspected Lassa Fever case, that patient is clearly receiving an identifiable special benefit over and above those accruing to the public. Nevertheless, the ultimate beneficiary of this testing is the general public, in knowing whether or not a highly dangerous disease actually exists in the community so that preventive action can be taken. If the patient was charged for the substantial costs of such tests, then the patient may well be hesitant to cooperate at a crucial time in the process of diagnosing and preventing further cases.

Using the same basis that GAO used for its estimate, we tested approximately 100,000 specimens at a cost of approximately $6.0 million in FY 1982.

Question: How much do you plan to spend on diagnostic testing in the current fiscal year and in fiscal year 1984?

Answer: Using the same basis that GAO used for its estimate, we project the following:

FY 1983 - approximately 90,000 specimens at a cost of approximately $5.8 million
FY 1984 - approximately 90,000 specimens at a cost of approximately $5.8 million

Question: Can the methodology used by GAO in developing its report findings be used by CDC in the future to substantiate the progress it is making in reducing unnecessary testing?

Answer: CDC is currently developing a sampling plan, for use in monitoring the progress in reducing unnecessary testing.

Question: The GAO also found that, although your testing services are supposed to be used as a resource of final resort for testing specimens, 46 percent of the specimens tested at CDC in fiscal year 1981 were not tested initially by commercial or State laboratories, as they should have been. Will your new February 1983 guidelines for screening specimens sent to CDC reduce significantly this very high level of unnecessary testing?

Answer: The new screening procedures have reduced the number of specimens submitted by approximately 13% since FY 1981. The GAO "46 percent not tested initially by commercial or State laboratories, as they should have been" was over-estimated because all specimens do not require that the accompanying test form be totally completed.

Question: Do you have a target for reducing the percentage of specimens that you test which have not been prescreened? If so, what is that target?

Answer: The objective is to eliminate testing of all specimens that have not been prescreened. The use of a new justification check list by the states has reduced the number of specimens submitted. CDC is currently developing a plan to assess the correct use of the check list by the States.

Question: The GAO study found that you were not recovering any of your testing costs and indicated that in fiscal year 1981 you could have collected $3.3 million in user charges from private health care providers and clinical laboratories. Why shouldn't the Federal government receive compensation for the expenses it incurred in performing tests for health care providers and laboratories who use this information in a profit-making business?

Answer: Specimens are not accepted directly from private health care providers and clinical laboratories unless (1) previous arrangements have been made with a State laboratory or a CDC scientist or (2) delaying test results by returning specimens would be harmful to the patient; the submitter is informed of proper procedures for the future. During a recent one-week analysis of all specimens received, 54 specimens (7.5%) were received directly from physicians/clinics/hospitals. Thirty-five were tested because previous arrangements had been made with CDC or States; 19 specimens were returned. Specimens are tested only if the service needed is not available at the State or local level and the service is pertinent to the control and prevention of public health disease problems.

HOSPITAL INFECTIONS

Question: You indicate on page 213 of your justifications that hospital-associated infections are estimated to occur in 5 percent of all patients admitted to U.S. hospitals. This problem was highlighted in a recent series of articles on infectious diseases which appeared in the Washington Post. Since this type of infection costs this country at least $2 billion or $3 billion a year it imposes a heavy burden on our very expensive health care system.

I'm glad to note that you will be continuing to fight this problem next year. Can you tell us how much you are spending on this effort currently and what your fiscal year 1984 budget will be?

Answer: Current year and FY 1984 obligations are estimated to be $2.8 million.

Question: How do we compare with other Western countries in incidence of hospital-associated infections?

Answer: We are not aware of any data on the incidence of hospital-associated infections in other Western countries.

LABORATORY IMPROVEMENT

Question: Under your laboratory improvement program you plan to analyze the performance of laboratory technologists in small laboratories throughout the country to identify problems that occur in the processing of clinical samples used to diagnose many infectious diseases. Of course we have all heard horror stories about faulty lab tests. What is the current rate of laboratory error in the U.S.?

Answer: Although rate of laboratory error has been estimated, a consensus of operational definition of "laboratory error" does not exist. This lack of consensus creates a serious problem which precludes establishing an estimate of "current rate." Errors can occur at various stages in the processing of a human sample; for example, when the sample is collected, packaged, and transported; when the package is opened upon arrival at the laboratory; and when clerical activities are performed. In addition, during the actual technical process, errors can result from faulty supplies and reagents, equipment malfunction, and human mistakes. Additional errors can occur during the final clerical process; for instance, in recording correct result and wrong patient. Other concerns include proper selection of tests, interpretation of results, and degree of accuracy and precision required for successful diagnosis and management of a patient. Between 600-1000 different tests are being performed in most diagnostic laboratories. Without an adequate data base giving us volume of testing, by test, we have not been able to develop a method for generating a useful numerical value to assign to error rate. For these reasons, the current rate of error in any of the described areas is unknown. Several attempts have been made to define and measure error. Although a satisfactory answer has not been found, we know what won't work and are closer to developing a system that can measure error rate and thus provide badly needed baseline data. One indicator of proficiency in a number of different test areas can be determined from current proficiency testing results. These results, however, are merely estimates of the best that laboratories can perform in a given technical area because, traditionally, laboratories assign their best people to perform proficiency testing samples.

Question: You plan to develop recommendations for improving the performance of lab technologists following your analysis. When will the work be completed and the recommendations become available?

Answer: Before making recommendations for improving performance of laboratories in the U.S., we must have performance data showing where error is occurring and why it is occurring. At least two more years will be required to collect and analyze such data as size of institution, workload, and methodology, and then to pull together groups of individuals for specific training areas and select the highest priority area. Meanwhile, a preliminary analysis has already been completed on the training needs of individuals and the nearly 1,000 institutions such as hospital and public and private laboratories who are currently sending technologists to CDC each year for the training necessary to improve their laboratory performance. It was found that most of the students trained in CDC courses will, upon return to their own institutions, supervise or teach laboratory specialities to other workers and revise their standard operating procedures manuals. The training courses are being modified to include additional emphasis upon these special skills within the technical subjects. Additional sessions will also be included on more effective communication/interpretation of complex laboratory results to physicians to aid in their treatment of patients. We have also initiated a pilot program conducted by telephone that is aimed at providing laboratory technologists

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with rapid response to their technical questions and problems while concomitantly providing CDC additional information about their training needs.

As the data base emerges that shows where and why performance problems occur, specifies technical problems, and identifies training needs, we will develop a consensus model. This model will enable CDC to more directly involve the public and private sectors in targeting tests and technologists for high priority training efforts.

DIAGNOSTIC TESTS

Question: GAO also stated in its report that an additional $662,000 in reimbursements from other Federal agencies should have been sought by CDC in fiscal year 1981. You disagreed with this estimate and said the amount was only $272,647. Regardless of which figure is accurate, why didn't CDC charge other Federal agencies such as the Department of Defense?

Answer: In FY 1981, CDC charged only the Veterans Administration for testing services. The charges were based on cost figures established several years earlier. The charges are currently being adjusted to reflect current actual costs; other Federal agencies will also be charged when the new costs are established. Based on the number and type of specimens submitted by other Federal agencies in the first half of FY 1983, the estimated annual recoverable costs will be approximately $300,000.

PURCHASE OF AIRCRAFT

Question: Once again this year you are proposing bill language that would allow you to purchase, hire, maintain, and operate aircraft. The explanation on page 197 of your justification indicates that you must maintain the ability to hire aircraft, but it says nothing about purchases. Do you intend to purchase any aircraft next year?

Answer: At this time, CDC has no plans to purchase any aircraft.

Question: If you don't intend to use this purchase authority in fiscal year 1984, why are you requesting it?

Answer: For the purchase of aircraft, this is stand-by authority. CDC does hire aircraft for testing new insecticides and formulations and for applying the insecticides when outbreaks of mosquito-borne disease, such as encephalitis, occur in populous areas where no other method can be used to control the spread of the disease.

ACQUIRED IMMUNE DEFICIENCY SYNDROME

Question: In discussing Acquired Immune Deficiency Syndrome you indicate that although the problem continues to be concentrated in New York and California, where 70 percent of the cases reside, 34 states have reported cases to the CDC. Can you tell us whether this disease has become a problem in the Midwest in general and in Wisconsin in particular?

Answer: Through April 3, 1983, fifty-two (52) cases of AIDS have been reported from these midwestern states: Illinois, Indiana, Kansas, Michigan, Minnesota, Missouri, Ohio, and Wisconsin. To date, one case has been reported from Wisconsin.

HOSPITAL INFECTIONS

Question: You indicate on page 214 of your justifications that you have a 1990 objective of reducing the incidence of hospital infections. Do you have a numerical goal and, if so, what is that goal?

Answer: By 1990, the incidence of nosocomial infection in acute-care hospitals should be reduced by 20% of what otherwise would pertain in the absence of hospital infection control programs.

Questions Submitted by Senator Quentin N. Burdick

1984 FUNDING

Question: An item of concern to me is funding for the Centers for Disease Control, and in particular the National Institute for Occupational Safety and Health. The fiscal year 1984 budget shows an increase of some $21 million in funding for the Centers for Disease Control; however, a decrease in funding is assumed for occupational safety and health. The budget also assumed the elimination of the training program for occupational safety and health. How many training programs are currently funded as a result of the training monies provided in FY 1983?

Answer: Fourteen (14) Educational Resource Centers and nine (9) small training programs are funded by the $5.76 million earmarked for training in the FY 1983 budget.

Question: Prior to the FY 1981 budget and recissions package, approximately $76 million went to the National Institute for Occupational Safety and Health. This funding has been reduced since that time to the current budget request of $54,620,000. Since 1981, how many programs carried out by the National Institute for Occupational Safety and Health have been reduced or eliminated?

Answer: The cuts in the Institute's budget from FY 1981 to FY 1983 have, for the most part, resulted in delays in completion of lower priority research projects and results rather than in eliminated programs. Reductions have been experienced in the Institute's general surveillance program of occupational safety and health problems through a delay in the initiation of the National Occupational Exposure Survey for Mining, a decreased integration of existing State surveillance data with the NIOSH nationwide system, and a delay in the analysis of the results from the National Occupational Survey. A surveillance program focusing in the occupational hazards experienced by divers has been eliminated. In the evaluation program for occupational safety and health hazards, reductions have been taken in the occupational cancer program, cardiovascular disease research,

reproductive health, noise-induced hearing loss research and psychological disorders. NIOSH has been unable to initiate two studies in the areas of neurotoxic disorders and dermatologic problems where current evidence indicates strong associations between occupational exposures and disease. Also, the reduction has delayed new efforts to develop performance standards for personal protective equipment other than respirators (i.e. hard hats, safety shoes and goggles) and in testing hearing protectors has been discontinued.

WORK-RELATED INJURIES

Question: The cost of work-related accidents, injury and illness has been estimated to be over $30 billion annually. Further, an estimated 95 percent of workers' compensation claims are paid for occupational accidents, while only 7 percent of the 1982 NIOSH budget is directed toward work-related injuries. Does your FY 1984 NIOSH budget provide for an increased research activity in work-related injuries?

Answer: NIOSH has recently defined the ten leading work-related diseases and injuries, and, over the next three years, will be focusing resources in these areas. Musculo-skeletal injuries, and amputations, fractures, eye losses, lacerations and tramatic deaths are numbers two and four on that list. We would, therefore, anticipate a greater level of effort in these areas in FY 1984.

Question: It is further estimated that in 1981-82 over 462,000 workers suffered work-related hearing loss and over 700,000 workers suffered work-related skin problems. There is much that is not known about occupational cancer. A prime example of worker-related illness is found in the coal industry--black lung disease. Does your FY 1984 budget reflect an increase in activity for any research in these areas?

Answer: The response to this question is the same as for the previous one, noting that work-related hearing loss, skin problems and occupational cancer are also on the list of ten leading work-related diseases and injuries as numbers eight, nine and three respectively.

Question: Does your FY 1984 budget assume any reduction in the activities or personnel at the Appalachian Laboratory on Occupational Safety and Health?

Answer: No. Three of the first four problems on the list of ten leading work-related diseases and injuries will be addressed by the two research divisions in Morgantown--the Division of Repiratory Disease and the Division of Safety Research.

NIOSH TRANSFER TO NIH

Question: I continue to have strong concerns over funding for research activities in occupational safety and health. It is obvious from the statistics that are available, that we have not solved the problems of occupational injury or illness. While I recognize the need for economy as much as the next person, it

would seem, on the whole, that we are being penny wise and pound foolish--especially if we take into consideration the astronomical cost of injuries and illness.

The Administration has previously gone on record as being opposed to the transfer of the National Institute for Occupational Safety and Health to the National Institutes of Health. There is legislation pending in the House of Representatives which would transfer NIOSH to NIH. What are your feelings on such a transfer?

Answer: I do not support the transfer of NIOSH from the Centers for Disease Control to the NIH. Due to significant differences between CDC/NIOSH and NIH in mission, orientation, operation, and constituents, the goals of NIOSH are best served by maintaining its current organizational location as part of CDC.

Question: Would you provide the reasons why you are opposed to such a transfer?

Answer: CDC is the principal agency of the Public Health Service concerned with the prevention of unnecessary illness and premature death. NIH, on the other hand, by stimulating and supporting basic investigator-initiated research, works to improve human health by acquiring new scientific knowledge. NIOSH and CDC are most compatible, each with their focus on operational research, and application of existing knowledge, field investigations, technical assistance.

Although there is some similarity between the research conducted by NIOSH and NIH, there is a significant difference in focus. Occupational safety and health research as performed by NIOSH focuses heavily on identifying and characterizing workplace conditions that cuase disease or injury and on recommending technologies for prevention. This requires an emphasis on subjects generally within the purview of NIOSH (e.g. safety, mining, and engineering) and outside the mission of NIH (e.g. regulation and service). CDC has long applied environmental and engineering controls to solve problems in the areas of vector-borne diseases and injury control.

CDC and NIOSH serve a different "constituency" than NIH. NIH relates to academic institutions and other organizations involved in conducting basic medical research. CDC relates to those groups primarily concerned with applying research findings: international, national, State and local health agencies, voluntary agencies, associations, and others in the public health community applying prevention programs, as well as industry, labor, and academia. The primary users of NIOSH are the occupational safety and health professionals in such settings and labor and industrial organizations.

CDC operates national surveillance systems not only for infectious diseases but also for chronic and environmental health problems through the network of State and local public health agencies. In occupational safety and health, this CDC expertise is important to assess the magnitude of health problems, monitor national trends, and conduct epidemiologic studies that will be instrumental to NIOSH in identifying effective control

mechanisms. NIH is not involved in such national surveillance activities.

There are other aspects of NIOSH which would be unique in the context of NIH. It is unlikely that these activities would prove compatible with the present mission of NIH:

NIOSH is required to respond to requests for health hazard evaluations. This activity results in a significant amount of service oriented research. This service activity brings NIOSH into daily contact, sometimes confrontational in nature, with industry. To do this work, NIOSH is authorized to use warrants and subpoenas in execution of right-of-entry and right-of-access to data. NIH neither has nor depends on field response capabilities, while CDC's expertise and success in conducting field investigations and epidemic response is well known.

NIOSH is authorized to recommend standards to the Occupational Safety and Health Administration (OSHA) and the Mine Safety and Health Administration (MSHA). This requires integration of results of NIOSH research, other research, and prudent public health concerns into major policy pronouncements. These recommendations are usually controversial because they require changes in the workplace environment and often have financial implications if implemented.

NIOSH is mandated to carry out programs to test and certify personal protective equipment. Most prominent in this is the testing and certification of respirators. NIOSH, in essence, regulates this industry and experiences the associated controversy and complaints.

SUBCOMMITTEE RECESS

Senator HATFIELD. The subcommittee will now recess until 8:30 tomorrow morning when we have our hearing on the budget for Health and Human Services departmental management, Office of Civil Rights, Inspector General, and other related areas.

[Whereupon, at 10:30 a.m., Thursday, April 14, the subcommittee was recessed, to reconvene at 8:30 a.m., Friday, April 15.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1984

FRIDAY, APRIL 15, 1983

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, D.C.

The subcommittee met at 8:30 a.m., in room SD–116, Dirksen Senate Office Building, Hon. Lowell P. Weicker, Jr. (chairman) presiding.

Present: Senators Weicker and Proxmire.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DEPARTMENTAL MANAGEMENT

STATEMENT OF DALE W. SOPPER, ASSISTANT SECRETARY FOR MANAGEMENT AND BUDGET

ACCOMPANIED BY:
RICHARD P. KUSSEROW, INSPECTOR GENERAL
DR. ROBERT J. RUBIN, ASSISTANT SECRETARY FOR PLANNING AND EVALUATION
BETTY LOU DOTSON, DIRECTOR, OFFICE FOR CIVIL RIGHTS
ANTHONY L. ITTEILAG, DEPUTY ASSISTANT SECRETARY FOR BUDGET

INTRODUCTION OF ASSOCIATES

Senator WEICKER. The subcommittee will come to order.

This morning we will conclude our budget hearings with the Department of Health and Human Services.

We will have testimony from Mr. Dale Sopper, Assistant Secretary for Management and Budget, and Richard Kusserow, the Inspector General.

Mr. Sopper, you are our first witness. Please introduce the people at the table with you and then proceed with your opening statement. I understand also Mr. Kusserow has a statement.

Mr. SOPPER. On my far left is Ms. Betty Lou Dotson. Ms. Dotson is the Director of the Office for Civil Rights, Department of Health and Human Services. On my immediate left is Mr. Richard Kusserow, Inspector General for the Department of Health and Human Services. And on my right is Dr. Robert Rubin. Dr. Rubin is the Assistant Sec-

retary for Planning and Evaluation and is the account manager for the policy research appropriation that is before you.

PREPARED STATEMENTS

Mr. Chairman, if I may, I would like to have my prepared statement, along with that of Richard Kusserow inserted into the record and just make a few brief remarks.

[The statements follow:]

STATEMENT OF DALE W. SOPPER

I am pleased to be here today and have the opportunity to present and justify the FY 1984 Departmental Management portion of the Department of Health and Human Services budget request. This category consists of five appropriations, four of which are considered by this Subcommittee--General Departmental Management, Office of Inspector General, Office for Civil Rights, and Policy Research.

The dollar resources for these appropriations represent only one-tenth of one percent of the total HHS budget. With these resources, the Secretary manages the Department; provides certain administrative and operational services to the Department's operating divisions and employees; identifies actual and potential instances of fraud, waste and abuse; fulfills responsibilities for enforcing the nondiscrimination laws in HHS programs; and provides for research into alternative policies in our health, social services, and welfare programs.

Our budget request in FY 1984 totals $288.6 million and 5,355 full-time permanent positions. In addition, we are also requesting a transfer of $16.4 million from the Social Security and Health Insurance trust funds to cover costs of services performed on behalf of benefit programs financed by the trust funds. Thus, the total obligational authority for FY 1984 is $305 million.

We are also requesting $9 million as an advance appropriation for FY 1985 to support first quarter costs of the State Medicaid Fraud Control Unit program.

Mr. Chairman, at this point I would like to summarize the major activities and budget highlights of each of the four appropriations.

General Departmental Management

First, the General Departmental Management appropriation is organized in two major activities -- Departmental Direction and Departmental Operations:

-- Departmental Direction supports those activities related to the Secretary's responsibilities for directing policy and management of HHS, and includes activities such as policy analysis, legislative liaison, budget formulation, personnel management, financial management, grants and contracts management, and legal policy affecting the entire Department.

-- Departmental Operations supports six major services for the Department's operating divisions which have been centralized for economies of scale and cost effectiveness. These include: central payroll and personnel data services; legal services provided for all of the Department's programs; a Grants Payment System which serves as a central payment and cash control point for recipients of HHS grants and contract awards; facilities engineering, which oversees all facilities and construction matters within the Department; administrative services provided to Department-wide headquarters staffs; and personnel and other administrative services provided to all of the Department's regional program components.

In FY 1984, we are requesting $170.0 million (plus a transfer of $8.0 million from trust funds) and 3,468 positions for General Departmental Management, an increase of $13.2 million above, but a decrease of 39 positions below, the FY 1983 level.

The requested $13.2 million net increase is actually less than the amount required -- $15.6 million -- to fund non-controllable, and other mandatory cost increases during FY 1984. These include an increase of $10.8 million for rental rate increases in office space and building management services required by the General Services Administration; $1.0 million for increased pay costs; $2.5 million for the continuation of special projects initiated in prior years; and $1.3 million for increases in other administrative costs such as travel, postage and freight rates, rentals, printing, equipment, supplies and unemployment compensation. The $15.6 million increase is partially offset by built-in decreases of $1.3 million for non-recurring costs associated with FY 1983 staffing reductions and special projects. We are not able to absorb these non-discretionary increases in FY 1984 without a further reduction in staff, below the reduced level reflected in this request.

Office of the Inspector General

To continue the essential work of the Office of Inspector General, the budget includes $88.3 million in budget authority and 1,378 full time permanent positions (plus a trust fund transfer of $6.0 million). We are also proposing an advance appropriation of $9 million to fund the first quarter grant awards for FY 1985.

In FY 1984, the OIG will concentrate on identifying the processes in the Department's programs which give rise to opportunities for fraud, waste and abuse. Specifically, the emphasis for audit and reviews will be directed toward Social Security, and health care financing programs, and internal management controls.

In line with this emphasis, the request includes $14.9 million and 352 positions for "Program Integrity and Validation" activities which were formerly included in the budgets of the Social Security Administration and Health Care Financing Administration. These activities, which involve criminal investigations of suspected cases of fraud or abuse, and special audits of the financial and administrative practices of health care providers, have been consolidated with other Departmental investigative resources in the Office of Inspector General to improve efficiency and avoid potential duplication of our audit and investigative efforts.

Office for Civil Rights

To support the Office for Civil Rights (OCR), we are requesting $19.4 million and 509 authorized positions. In addition, $2,350,000 would be transferred from the Social Security and Health Insurance trust funds. The total amount requested represents an increase of $200,000 over the FY 1983 level.

OCR is the principal agency responsible for enforcing non-discrimination laws in health and human services programs. These laws prohibit discrimination on the basis of race, color, national origin, handicap, and age. There are about 230,000 group and institutional providers subject to the civil rights laws. OCR's responsibility is to ensure that all recipients of Department funds are aware of their civil rights obligations and have taken the necessary steps to comply.

Since 1981, OCR has undertaken an innovative and more effective compliance approach which has allowed us to place more emphasis on compliance reviews, voluntary compliance and

outreach efforts. The FY 1984 budget for the Office for Civil Rights will preserve and continue this approach.

Policy Research

The FY 1984 requested funding level of $11 million will support research in the areas of health, income and employment, and human services policy. This research provides information for the Department, other Federal agencies, the Congress, States and others about human resource policies and programs, both current and new, and about the anticipated effects of policy and program changes.

In this account, the Department emphasizes short-term, focused studies that enable a quick response changing policy needs and priorities. This is a shift away from the large-scale multi-year experiments and projects which were supported in the past. We believe this strategy will produce studies targeted on some of the most significant current issues, will result in more timely and policy-relevant findings, and will enable us to be more responsive to the needs of both the Administration and the Congress.

Summary

In conclusion, Mr. Chairman, I believe that this is an austere but realistic budget that provides sufficient resources to carry out the array of national responsibilities levied upon HHS Departmental management. I urge your approval of this request and thank you for your consideration.

Biography of Dale W. Sopper

Dale W. Sopper was sworn in as assistant secretary for management and budget, Department of Health and Human Services, Sept. 24, 1981. He had been the acting assistant secretary since June 27, 1981, and from January 1981 to June 1981 had served as acting assistant secretary for legislation.

Before that Sopper, who has been with the department and its predecessor, the Department of Health, Education, and Welfare, since 1965, was director of program coordination in the Office of the Assistant Secretary for Legislation from July 1978 to January 1981.

He is the HHS Secretary's principal advisor for management, administrative and budget policies. His responsibilities include overseeing development of the department's budget and providing department-wide guidance on general management operations and major policies in HHS in such areas as grants, contracts, financial management and automatic data processing systems.

Sopper was born in Allentown, Pa., Dec. 24, 1941. He received his bachelor's degree, with honors, from Lehigh University, Bethlehem, Pa., in June 1963, and did graduate study at the University of Minnesota from June 1963 to June 1965.

He joined the department in July 1965 as a claims insurance specialist with the Social Security Administration's Office in Kansas City, Mo. From July 1967 to November 1969, he was a management intern for SSA and had assignments as a financial systems analyst in the Office of the Assistant Secretary for Community and Field Services and as staff assistant in the Office of the Assistant Secretary for Health and Scientific Affairs. He served in the latter office as a management analyst from November 1969 to April 1972.

Sopper started in the Office of the Assistant Secretary for Legislation in April 1972 as a special assistant for health legislation. He became legislative officer for health in May 1973, senior agency legislative officer in July 1974, was acting deputy assistant secretary from April 1975 to January 1976 and served the first of his two stints as acting assistant secretary for legislation between January 1977 and April 1977.

Sopper has had a distinguished career in the department, receiving several honors for his performance: Distinguished Service Award, March 1980; Secretary's Letter of Commendation, August 1979; Secretary's Special Citation, August 1975; and the Superior Service Award, December 1974.

Sopper is married, has two daughters and resides in Reston, Va.

Statement of Richard P. Kusserow

I am pleased to appear before you today to discuss the President's FY 1984 budget proposal for the Office of Inspector General (OIG). For FY 1984, we are requesting $94,263,000, and 1,378 positions, including $24,871,000 to support the State Medicaid Fraud Control Units (SMFCU). The SMFCU budget constitutes an $11,475,000 reduction from the FY 1983 level as a result of changing the funding mechanism. Within this level the, OIG direct operations budget is increased by $1,647,000 (approximately 2.4%) from the FY 1983 appropriated level. These direct operations dollars will support the audit, investigation, integrity and inspections functions in addition to the administrative costs and oversight of the SMFCU program.

In testifying for the first time as HHS's Inspector General before the Committee last year, I committed myself and the Department to more efficient utilization of our resources through the implementation of a comprehensive and systematic strategy for combatting fraud, abuse and waste in HHS programs. At that time, I was talking about a two stage effort. First, we redirected our audit, investigative and integrity resources from a primarily reactive to an active focus on the large dollar, managerially complex programs such as Social Security and Medicaid and Medicare. This necessarily required realigning OIG resources to parallel major departmental programs such as Social Security, Medicaid and Medicare. Second, we reviewed other departmental resources performing OIG type audit and investigative activities to determine whether any duplication existed. As a result, the department consolidated in the Office of Inspector General program integrity and validation functions of the Social Security, Medicaid and Medicare programs. I believe this consolidation allows us to better target our investigative resources, and reduce duplication among departmental operating divisions.

Mr. Chairman, at this point, I would like to summarize what has been accomplished by OIG since last year and the direction in which the office will move in FY 1984. I believe that the significant progress we have made shows that we are on the correct approach and bodes well for significantly greater productivity in FY 1983 and 1984.

ACCOMPLISHMENTS

One of the key accomplishments over the past year has been to reorganize the Office of Inspector General in order to maximize productivity and effectiveness. This reorganization supports our major change in priorities and refocuses resources from grant and contract close-out audits to combat fraud, abuse and mismanagement in the Social Security Medicaid and, Medicare programs. As I noted

earlier, a cornerstone of our efforts to improve effectiveness of the OIG was to consolidate in the OIG, the audit, integrity and investigative functions for Social Security and Medicare/Medicaid. These new functions, the Health Financing Integrity office and the Program Integrity staff, are specifically dedicated to the elimination of fraud and waste in the Medicaid/Medicare and Social Security programs, respectively.

We established a Civil Fraud Division in our Office of Investigations to manage administrative mechanisms to pursue fraudulent activities associated with the health care financing program. Incorporated in this Division is an Administrative Sanctions Division to monitor all such actions pending in the Department.

We also expanded our Office of Audit to include one of the first EDP Audit Divisions in the Federal government; its principal mission is to review the design and development of departmental computer based systems including the Social Security Administration's Modernization plan.

Some of the other significant milestones achieved during the preceding year include:

- o Increased the number of successful prosecutions over the last two years. In the first 6 months of this year, we have already doubled all of last year's efforts.
- o Increased the amount of fines, restitutions and settlements at a very significant rate.
- o Expanded management's commitment to seek recovery with cost avoidance. In the first 6 months of this fiscal year, we have already exceeded the entire previous year.
- o Our State Medicaid Fraud Control Units (SMFCU) indicate that direct overpayments, recoveries, restitutions, and fines will reach $25,000,000 for FY 1983. As of December

1982, these units have been responsible for 857 convictions.

Our office has a history of using and conducting research to develop computer techniques to detect and deter fraud, abuse, and waste. This office developed the now famous computerized information retrieval system called HEWCAS (HEW Computer Audit System).

Over the last year our use of computer techniques has increased substantially. We spearheaded the development of computer matches and more sophisticated screening and analysis techniques. Matches, which involves the comparison of two or more files, identify possible incidences of recipient fraud in benefit programs. Among the screens we have developed are those designed to find persons using invalid social security numbers, and medical providers submitting erroneous bills. We have developed approximately two-thirds of all Federal computer matching programs. Because of our expertise in this area, we are called upon to give technical assistance to Federal and State agencies and we make our techniques and software available to all governmental units.

Currently we are instituting the Civil Monetary Penalties legislation. It permits the Department to impose penalties and assessments administratively for the filing of false or certain other improper claims in the Medicare, Medicaid or Maternal and Child Health Services block grant programs. The monetary penalties which we may assess under this program will serve as a deterrent by convincing a would-be defrauder that the risk of discovery and punishment for filing false claims far outweighs the potential reward.

The recent extension of the Hotline to a nationwide capability has proven useful. During the first 6 months of FY 1983, we have received 2,198 complaints. Over 50% of the allegations refer to

Social Security, Medicaid, and Medicare abuses. This new nationwide capacity has resulted in three times the number of calls previously recorded.

The OIG continues to serve as an objective resource for both the Congress and the Department. We have presented testimony on a variety of subjects such as the End Stage Renal Disease program of HCFA, the use of tamperproof Social Security cards, and the need for computer matching in government programs.

As part of our goal to eliminate the potential for fraud, abuse and mismanagement, we are actively participating in the Department's legislative and regulation review process and, through our recommendations, have made a significant number of cost-saving proposals to the Department. We now review proposed program changes to assure that they are framed with due regard to their effect on the control of fraud and abuse and that they contribute to the efficiency of program operations.

Finally, we have actively participated with other Inspectors General on the President's Council on Integrity and Efficiency. I am presently co-chairman of the Long-Term Computer Matching Committee, and of the Prevention Committee; and chairman of the Computer Security Committee and of the Health Care Financing Integrity Project. Additionally, we are active in several other important projects such as: Convicted Providers, Payroll Operations, Training, Performance Evaluation, Investigation, Law Enforcement, Computer Audit, and Debt Collection.

Prevention

We are now at a point in the history of the OIG which I believe is a major turning point for us. We are moving from a reactive organization to an active institution, with emphasis on preventing fraud, waste and mismanagement in the Department's programs. This, I believe, is what the Congress intended. The HHS/OIG has expanded efforts to address before-the-fact problems by eliminating the program weaknesses or "loopholes" which permit system abuses. A

recent survey by the President's Council on Integrity and Efficiency (PCIE) indicates that this office is now in the forefront in implementing innovative techniques to prevent fraud, abuse and waste, for example the Management Implications Report (MIR). The MIRs represent a refocusing of the investigative process from an exclusive concern with the individual case to a concurrent consideration of the systemic weaknesses that permitted the fraudulent or abusive act to occur. OIG investigators are now required throughout the course of each investigation to seek systemic weaknesses and to report such weaknesses to a systems staff for analyses to determine remedial measures.

Conclusion

In closing, Mr. Chairman, I want to assure you that concerted and comprehensive efforts exist within the Office of Inspector General to combat fraud, abuse and mismanagement. Moreover, I want to emphasize my commitment to continue to take an active role in pursuing the following objectives:

- Serve as the "watchdog" for Department funds and programs with priority to high cost programs;
- Act as an "Agent for Change" for programs and systems to prevent or limit the occurrence of opportunities which lead to fraud, abuse and mismanagement;
- Expand cooperative initiatives with all Federal departments to create more sophisticated techniques and tools to conduct our work; and
- Maximize our productivity and effectiveness.

Thank you for this opportunity, Mr. Chairman. I will be pleased to answer any questions the Committee may have or provide any additional information for the record.

BUDGET REQUEST

Mr. SOPPER. Mr. Chairman, as you know, departmental management is made up of four appropriations—five actually—four of which are considered by this subcommittee: general departmental management, the Office of the Inspector General, the Office for Civil Rights, and policy research.

We are proposing $289 million and 5,355 full-time permanent positions in the fiscal year 1984 budget request for these four appropriations.

Mr. Chairman, at this point I would like to comment on what makes up the departmental management budget.

Nearly 80 percent of the positions in departmental management provide direct operational services on behalf of the Department's operating divisions.

One thousand three hundred and seventy-eight positions support the Office of Inspector General, which identifies actual and potential fraud, waste, and abuse and makes recommendations to avoid misfeasance of funds;

Five hundred and nine positions are for the Office for Civil Rights, the principal agency responsible for enforcing the nondiscrimination laws in HHS programs;

And 3,468 positions in the general departmental management appropriation, which provides centralized HHS-wide services to the Department's operating divisions and provides policy review and management direction for the Secretary.

Within general departmental management, 2,287 positions or 66 percent provide operational services on behalf of the operating divisions. These services are provided centrally to take advantage of economies of scale and other cost efficiencies.

These positions provide for payroll services for all HHS employees, legal services for all of our programs, and personnel and administrative services for all regional office operations.

One thousand one hundred eighty-one positions, or 34 percent of the general departmental management total, provide policy review and management direction for the Secretary on behalf of all the Department's operating programs.

In this light, slightly fewer than 1,200 positions, about 0.08 percent of the Department's total positions, in departmental management assist the Secretary in developing policy and providing management direction to the Department's programs and employees.

At this point I would like to summarize our fiscal year 1984 budget request for each appropriation.

For general departmental management we are proposing $170 million. This request will support all built-in cost-of-living increases, essentially all of which is the increased cost of office space rental. These increases have been partially offset by small staffing reductions.

For the Office of the Inspector General the budget includes $88 million and 1,378 positions. Of the $88 million, $15 million and 352 posi-

tions are earmarked for program integrity and validation investigations and reviews which were formerly carried out by the Social Security Administration and Health Care Financing Administration.

Consolidating these activities in the Office of the Inspector General reduces duplication of the Department's investigative activities and improves management efficiency.

Our request for the Office for Civil Rights includes $19.4 million in budget authority and 509 positions. At this level the Department can fulfill its responsibilities for enforcing nondiscrimination laws affecting health and human services programs.

Finally, we are proposing $11 million to continue essential projects in the policy research program. The fiscal year 1984 program will focus on short-term studies and enable a quick response to changing policy needs and priorities.

In conclusion, Mr. Chairman, I believe this is an austere but realistic budget that provides sufficient resources to carry out the management responsibilities of the Secretary.

If you have no objection, Mr. Chairman, Mr. Kusserow would like to make a statement.

Senator WEICKER. Fine. Go right ahead.

INSPECTOR GENERAL BUDGET REQUEST

Mr. KUSSEROW. Mr. Chairman, for the sake of brevity I could submit my statement for the record and make one or two comments.

OFFICE OF THE INSPECTOR GENERAL OVERVIEW

This last year, we have undergone a lot of reorganization and functional transfers to more efficiently utilize our resources, and these changes are beginning to show some good results. In the first 6-month period of fiscal year 1983 which has just ended, we have 426 convictions, which is double the entire last year's effort. Also we have about $500 million in financial findings with which management has concurred that will avoid costs as well as result in recoveries to the Department. That is also in excess of the entire last year's effort.

Thus, we feel that the redirection of our audit and investigative efforts are beginning to show some results.

Senator WEICKER. Are there any further statements?

CIVIL RIGHTS BUDGET REQUEST

Ms. DOTSON. I have a brief statement.

Senator WEICKER. Well, you go right ahead.

Ms. DOTSON. Thank you, Mr. Chairman.

For fiscal year 1984 the Office for Civil Rights is requesting $21.7 million in obligational authority and 509 authorized positions.

This budget we feel will enable OCR to continue to enforce the nondiscrimination statutes effectively. Basically this will be accomplished through three interrelated activities: by conducting on-site compliance reviews, by voluntary compliance and outreach efforts, and by investigating complaints of discrimination.

As Mr. Sopper has indicated in his statement, OCR has undertaken an innovative compliance approach which places greater emphasis on compliance reviews, voluntary compliance, and outreach efforts. This approach, which we term preventive civil rights, is designed to protect the rights of a larger universe of health and human services beneficiaries.

For example, in fiscal year 1984 we plan to expand the number of project reviews, which is a new initiative undertaken this year, to stimulate cooperative compliance efforts between program recipients and health and human services.

The objective is to attempt to resolve compliance problems on an expedited basis through prompt negotiations and the provision of technical assistance.

We will also conduct approximately 270 compliance reviews, and we expect to resolve all complaints of discrimination on a timely basis.

In conclusion, Mr. Chairman, we feel that the budget request will provide the resources necessary to preserve and continue the priorities which we have established for OCR and civil rights enforcement.

Thank you, Mr. Chairman.

Senator WEICKER. Thank you.

Dr. RUBIN. I will pass in the interest of time.

Senator WEICKER. Senator Proxmire.

STAFF LEVELS OF DEPARTMENTAL MANAGEMENT

Senator PROXMIRE. Mr. Sopper, you have had a very distinguished career. Your resumé indicates you have received the Secretary's special citation. I have no question about your ability. However, some disturbing questions have been raised with regard to the administration of the Department, and I hope you can help me answer those questions.

Over the last 2 years the administration has placed its emphasis on consolidating the Department's programs, eliminating Federal redtape and shifting the administrative burden to the States. In the normal course of events one would expect that this would sharply reduce the bureaucracy at the departmental level. However, staffing under the departmental management function, including the Offices of the Inspector General and Civil Rights, will decline by only 6 percent between 1982 and 1984 under the proposed budget, and the total budget will actually increase by $41 million, a total of 17 percent, over the 2 years. Why haven't you been able to do a better job of reducing the departmental management budget and staff?

Mr. SOPPER. Well, I think we have done a very credible job, Senator, in terms of reducing the departmental budget in terms of the staff. I think in terms of the way you phrased the question we've got several interactions taking place here that I think we need to focus on. No. 1, in terms of general departmental management, which is the Office of the Secretary as most people perceive it, we have reduced staffing from the fiscal year 1982 level of 3,831 full-time equivalents to a fiscal year 1984 level of 3,614 full-time equivalents, which is a reduction of 217 work-years.

However, in the Inspector General's area we have added positions because of the functional transfer of staff from the Social Security Administration and the Health Care Financing Administration in order to achieve what we think are greater efficiencies for investigations and audit activities.

So in terms of the overall departmental management total, which is comprised of these two appropriations plus two other appropriations, these significant real reductions, offset by functional transfers, do not show up very sharply. That is to say, the Office of the Inspector General has increased approximately 370 positions as a result of locating these investigative functions in the Office of the Inspector General.

Senator PROXMIRE. The reason that I asked that question is because the administration's rhetoric has losses pretty strong. They talk about consolidating Department programs, eliminating Federal redtape, and shifting the administrative burden to the States. But I see a pretty modest reduction in personnel—despite from 3,791 to 3,468—all that strong rhetoric. That was the reason I asked.

Mr. SOPPER. We also have to deal with the situation in the legal area that has arisen in the past few years where the number of cases pending in which the Secretary is the defendant has increased from approximately 21,000 to the range of 24,000 to 25,000.

One of the things we have done in this budget is reallocate resources into the General Counsel's office in order to deal with this increased workload.

GENERAL COUNSEL STAFF

Senator PROXMIRE. Your justifications indicate a constant level of staffing in your General Counsel's office—58 in 1982 and 58 in 1984.

Mr. SOPPER. That's in terms of the policy direction that the General Counsel's office provides. In terms of legal services—the operational aspect of defending HHS against litigation—we have increased the resources in this area.

GRACE COMMISSION REPORT

Senator PROXMIRE. The number of positions in legal services is scheduled to drop from 636 to 587 between 1982 and 1984.

As I'm sure you know, a task force of the President's private sector survey on cost control studied your departmental management operations and made a number of critical findings. I would like to get your comment on two of these findings.

First, the task force found that "the problems of layering and duplication, conflicting responsibilities and authorities, and lack of accountability were repeatedly identified in every interview conducted. The overwhelming consensus of those interviewed was that these factors represent major inhibitors to effective management within HHS."

Do you agree with that point?

Mr. SOPPER. Well, Senator Proxmire, I don't feel that I'm really in a position to comment on that finding, because as you know that report

is a preliminary tentative draft and the Grace Commission is meeting today, I believe, to consider the public comment that has been turned into it by individuals who have looked at that report. They are going to be conducting an open meeting today, and that report may be redrafted. That report has not yet been presented to the executive branch as an official report of the Grace Commission.

Senator PROXMIRE. It was submitted to the Congress on April 5, 1983, a few days ago. I have a copy of the transmitted letter here.

Mr. SOPPER. I don't know quite what the commission said when they submitted the report, but it is not the final report.

DRAFT RECOMMENDATIONS OF GRACE COMMISSION

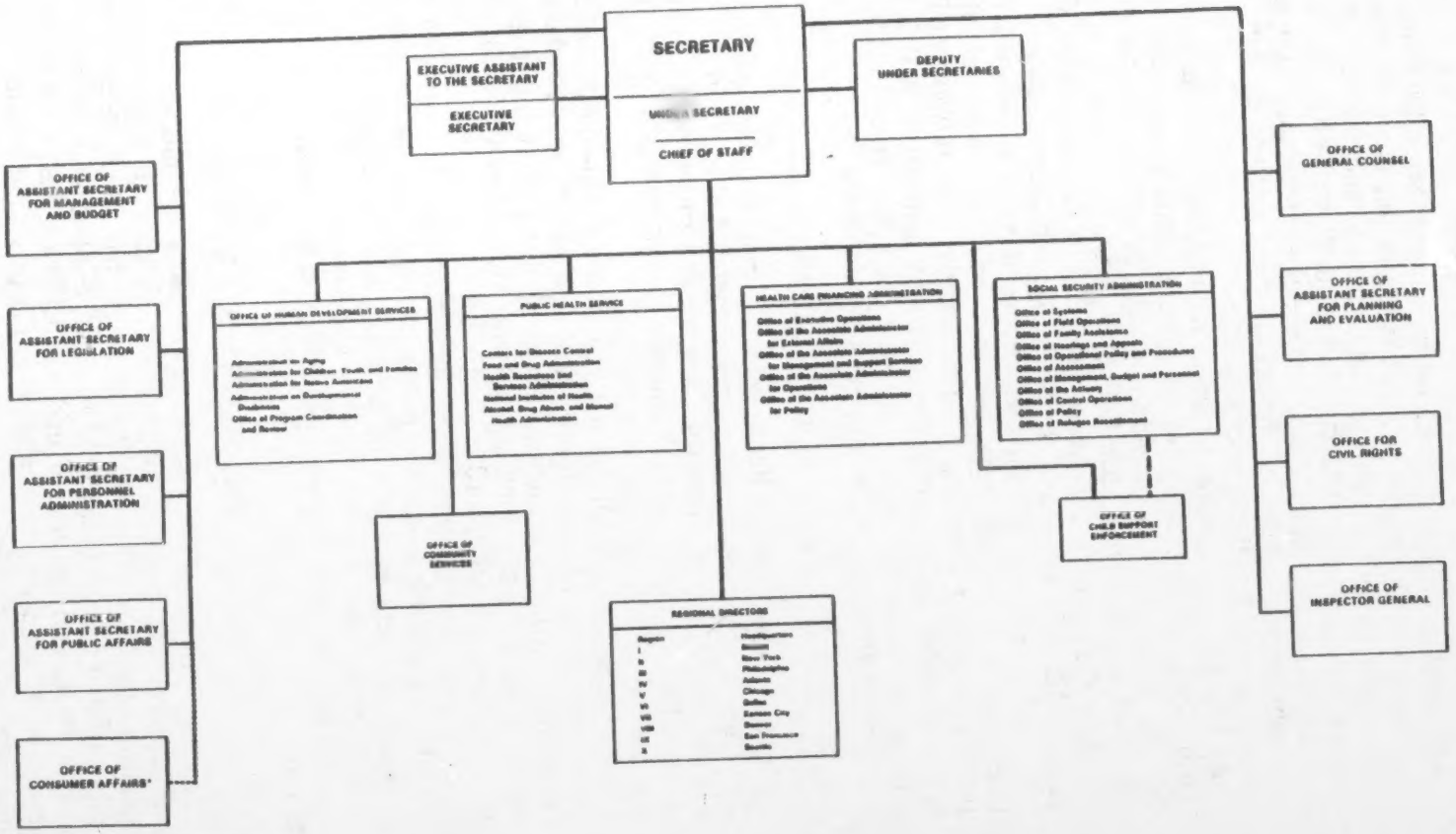
Senator PROXMIRE. Well, as administrator do you have any reaction to that charge? I can't understand why you can't respond. This hearing is the last time we will have a chance to discuss this issue with you this year.

Mr. SOPPER. I think one of the problems of interpreting that particular report, which just looked at one facet of Department operations, that I would react to is that of placing the findings in the proper context. We have two other task forces that looked at HHS. There was the task force on social security and there was a task force on the Public Health Service and the Health Care Financing Administration. We have not seen those reports. So we don't know how the reports from those two task forces are going to fit in with this task force report.

If I may, Senator, what I would like to do is insert into the record a chart, if you have no objection Mr. Chairman, of how the Department is organized.

[The information follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES



*Located administratively in HHS, but reports to the President

BREAKDOWN OF CHART

Mr. SOPPER. I think it is important to note, Mr. Chairman, the Department currently has, as you can see from this chart, eight staff divisions which provide support to the Secretary, and then it has, as you can see, five operating divisions. Each of these staff divisions has certain responsibilities in various functional areas whereby they exercise either oversight responsibilities on behalf of the Secretary or they have in some cases line functional responsibilities.

As I said in my opening remarks, of the 3,000 positions, in excess of 3,000 positions that we have in general departmental management, 2,287 of those positions provide operating support to the divisions that are listed on that chart: the Office of Human Development Services, Office of Community Services, Public Health Service, Health Care Financing Administration, and the Social Security Administration.

At HHS we have consolidated various services at the departmental level and are providing them departmentwide for reasons of efficiency. If the Department were organized differently, those services would have to be provided by the operating divisions themselves, and I am not sure, to the extent the services are now being performed centrally, they could be performed as efficiently on a decentralized basis.

GRACE COMMISSION FINDINGS FOR OIG

Mr. KUSSEROW. I would like to add, if I may, Senator, that the Grace Commission report contained no recommended changes in the staffing level of the Office of Inspector General, and suggested no diminution of the Office of the Inspector General's role or changing of its role. So that portion of it remains unchanged.

Senator PROXMIRE. Well, let me just proceed with these questions. I don't mean to be highly critical. I just don't know enough about your Department to make a judgment myself. But I do want to get your responses so that I can think about them. Maybe you could supplement your responses for the record.

Mr. SOPPER. Once we have the final report of the commission and after they've taken into account public comment and the reaction that is presented to them at the open meetings and the executive branch is given a report and we formulate a response to it, I'd be pleased to come in and sit down and discuss it with you or submit a written report to you.

GRACE COMMISSION REPORT COMMENTS

Senator PROXMIRE. The task force reviewed the mission statements and departmental functions for your staff divisions as well as your four operating divisions. Their review showed that justification exists for both staff and operating divisions to claim responsibility for a particular area or issue, and because of this conflict there was a substantial expenditure of time and resources with disappointing results. The task force referred to decisions that were deferred, delayed, or simply not made at all. And they talked of turf battles.

Is that a fair appraisal of what is going on in the Department?

Mr. SOPPER. Well, again, I don't know what specific examples they are referring to, Senator.

Senator PROXMIRE. Are you aware of turf battles?

Mr. SOPPER. I don't think there are any turf battles in the sense of people fighting over what areas of responsibility they are expected to exercise stewardship for. There may be differences of opinion, Senator. For example, the Assistant Secretary for Planning and Evaluation and the Assistant Secretary for Health might disagree on a substantive matter. If one considers that to be a turf battle, then, yes, those things do go on in the sense that the Assistant Secretary for Health may have his own position.

Senator PROXMIRE. I'm talking about the turf battles between the operating divisions and the staff divisions.

Mr. SOPPER. Like I say, Senator, I'm not aware of specific examples they are citing in terms of turf battles. If they are using issue differences, differences of opinion to reflect turf battles, yes, you do have differences of opinion in the Department about what advice the Secretary should follow just as there are differences of opinion within congressional committees.

Senator PROXMIRE. It's a matter of determining who has responsibility.

Mr. SOPPER. Well, I think the delegations from the Secretary about responsibility are very clear in the Department.

GRACE COMMISSION REPORT SAVINGS

Senator PROXMIRE. The task force concluded the operating divisions were capable of operating autonomously and recommended that a substantial amount of authority currently shared at the departmental management level be decentralized. If this approach were implemented the task force believes that the size of the various staff divisions could be reduced dramatically. The task force estimated a first-year savings of $48.1 million associated with the reduction of 1,674 full-time personnel.

Do you have any reaction to that estimate? That's quite a saving.

Mr. SOPPER. Again, Senator, let me say that the executive branch of the Government does not operate in a decentralized fashion. The executive departments, as you know, are in a hierarchical relationship to the Executive Office of the President, and in fact one of the initiatives that the administration has undertaken under the leadership of——

Senator PROXMIRE. I'm not talking about telling departmental management to get lost. I'm talking about cutting some of the responsibilities sharply and decentralizing some of those responsibilities. The task force did say a substantial amount of the authority is currently shared.

Mr. SOPPER. Well, I guess what I am saying is, in terms of the positions that are in the Office of the Secretary, approximately 66 percent of those positions that make up the Office of the Secretary are operational positions. They are not policy direction positions. They do work on behalf of the operating divisions on a centralized basis. If that work is not done by the Department on a centralized basis, then the func-

tions still have to be performed, and they'd have to be performed out in the operating divisions. That will take resources.

Senator PROXMIRE. Then you would dispute the argument that you could save $48.1 million and 1,600 people?

Mr. SOPPER. I have not done a detailed analysis and review of that report, Senator, because as I indicated to you, it's a preliminary tentative draft.

To expand my previous response with a few examples of the things I was talking about in terms of centralized services, the payroll at the Department of Health and Human Services is a centralized payroll system. We are one of the few executive departments in the Government that has one payroll system for the entire Department. In fact, we were cited by the task force on personnel—there was a Grace task force on personnel—as a model to be followed by other executive departments because we had one personnel system in HHS. And it was all centralized at the departmental level.

Another example of centralized services are the legal services that we provide to all the Department's operating divisions. Support for all of the litigation and legal advice to the Department's operating components comes out of the positions that are allocated to the Office of the Secretary. That work has to be done, Senator. If it's not done on a centralized basis under the General Counsel, then it would seem to me that you would have to replicate within the operating divisions legal support staff to provide the same kind of function that is now being done on a centralized basis.

So I guess I'm just saying I don't understand how the conclusions are arrived at in the face of the fact that 66 percent of the positions in the Office of the Secretary are operating positions supporting the operating divisions.

Senator PROXMIRE. Well, maybe this statement will help. This is one of the task force conclusions. "Our conclusion is that the existence of large numbers of people in Department management staff functions with roles and responsibilities that conflict with the operating divisions has resulted in the creation of a great deal of activity in which the staffs tend to create work for each other. This process tends to feed itself through turf battles that dilute the efforts of the staffs in performing their primary role of providing advice, counsel, and support to the Secretary."

Mr. SOPPER. I understand what you are reading to me, Senator. I have looked at that report. We have not done a detailed analysis of it because it is not considered final.

I'm not sure that the point that you and I have been discussing here about the magnitude of support staff that are providing centralized services is reflected in that document. We'll just have to see what finally is presented to the executive branch as the committee's final report on HHS.

GRACE COMMISSION FINDINGS ON POLICY RESEARCH

Senator PROXMIRE. You are requesting $11 million for policy research at the departmental level next year, a cut of $3.7 million from your current budget. The task force report of the President's private sector survey found the work funded with these dollars to be redundant to research programs of the operating divisions. The task force also found the execution of research at the departmental level relieves departmental management of the responsibility for creating an effective research agenda within the operating divisions. The task force report cites a review conducted under the previous administration which talked about "the sheer amount of staff time involved in dealing with redtape rather than substance."

The task force concluded that the funding for departmental policy research should be eliminated.

My question is why shouldn't this work be done at the operating division level?

Mr. SOPPER. If you have no objection, I think I will let Dr. Rubin, who is the account manager of policy research, respond to that.

Dr. RUBIN. I think what this preliminary report misstates and misunderstands is the function of the policy research account. As you well know from your involvement in one of the pieces of that account, what the policy research account is designed to do is to fund cross-cutting research. That is to say, issues that cut across several operating divisions.

You mentioned earlier the turf problems. I think that it is unreasonable, when you have two operating divisions with limited budgets, to expect them to give up the pieces of their own research budgets which have been limited to fund future policy evaluations——

Senator PROXMIRE. Doctor, let me interrupt for a minute to read from this report. It may help you in responding.

One of the reports' conclusions is "Departmental management conducts program-relevant policy research, while the operating divisions conduct policy-relevant program research. These descriptions illustrate the underlying similarity in research missions, as opposed to the subtle distinctions the Department management applies to justify the continuation of duplicative research operations at two distinct management levels within HHS."

Dr. RUBIN. In terms of the duplication, I think that we can make a good example there. Both my office and the Office of Research in the Social Security Administration do research on retirement and retirement-related issues. However, there is no redundancy, because one of the charges of my office is research oversight for the entire Department, which is a function that, at least in the preliminary draft, the Grace Commission found to be worthwhile and something that ought to be continued.

As a result of that we go to great lengths to assure that there is no redundancy in research and in point of fact serve as catalysts to perform this cross-cutting research in a way that serves the Secretary.

I think that that is the major reason that I believe the policy research accounts ought to remain at the $11 million request level.

GRACE COMMISSION FINDINGS ON PLANNING AND EVALUATION

Senator PROXMIRE. You're requesting $7,889,000 and 126 positions next year for the Office of Assistant Secretary for Planning and Evaluation. The task force report of the President's private sector survey on cost control cites a number of internal Department documents that question the value of policy evaluation within the Office of the Secretary.

For example, a study by the Office of the Assistant Secretary for Planning and Evaluation concluded "The evaluation process does not serve the needs of policymakers and program managers."

A PHS study found that one of the major reasons the evaluation process is "involved and time consuming is that the approval for responsibility for projects is centralized in the highest level of a large, many layered organization."

The task force recommended eliminating the planning and evaluation function at the Secretary's level and leaving it to the operating divisions at a saving of $10.5 million. How would your program be affected if you delegated responsibility for planning and evaluation to the operating divisions?

Dr. RUBIN. I think, Senator, you are confusing apples and oranges in your question. The $10.5 million represents the Office of the Secretary's evaluation funding, and my understanding of the report that you cited is that they do not believe that evaluation ought to be performed in the Office of the Secretary; they believe that the operating divisions ought to perform evaluations separately. That's point No. 1.

No. 2, my understanding of the report was that they are not questioning the need for planning within the Office of the Secretary, albeit at a much lower level, but the dollars associated with it are not with the 126 positions, but rather with those positions associated with performing the evaluations centrally.

I should point out that several Secretaries previous to the current Secretary have felt a need to have an independent evaluation process, and as Mr. Sopper said, I think that when we do receive the finalized report rather than a draft that is yet to be commented on publicly we would take a look at that, and I'm sure Secretary Heckler would, in conjunction with the Office of the President, make the appropriate changes.

GRACE COMMISSION FINDINGS ON HHS MAIL HANDLING

Senator PROXMIRE. Mr. Sopper, the task force report was highly critical of the way you handled your mail. They found it took 58 days to prepare a letter for the Secretary's signature compared to 18 days for the Department of Defense and 20 days for the Veterans Administration. The task force identified 26 separate steps in the correspondence clearance process and estimated that you could cut time devoted to the

process by 39 percent, correspondence personnel by 72 percent, and save $2.4 million a year by restructuring the correspondence control and clearance process.

How do you respond to that recommendation?

Mr. SOPPER. We view what the task force is saying as a preliminary document. I should say that even before the task force began to look at this matter, HHS former Secretary Schweiker was very much concerned about the time taken to respond to HHS mail. He had initiated some new procedures in terms of mail response which are now being implemented, and will speed up the response to mail.

Senator PROXMIRE. Can you tell us what your goal is with regard to response times. Fifty-eight days sounds appalling.

Mr. SOPPER. I think the objective is to try to get the response time down to 30 days.

Senator PROXMIRE. That would still be higher than the response time for the Department of Defense or the Veterans' Administration.

Mr. SOPPER. I can't comment on that, Senator, without knowing what the data base was for either Defense or Veterans, whether the response that was provided back to the individual who sent the incoming letter was a final response or an interim response. It has been departmental policy—and I have not seen any of these other reports—to try to provide a full and complete response to someone writing the Department rather than just give them a partial answer. Obviously, if that is the basic policy, sometimes it will take longer to provide a complete response. And, as you know, we get a lot of fairly detailed, involved policy inquiries to HHS from both the Congress and outside constituents.

Senator PROXMIRE. Why should your responses be any more involved than those of the Department of Defense which takes a third the time you do to respond?

Mr. SOPPER. Well, since I haven't seen the data you are referring to, I cannot compare the kinds of mail that are coming into the Department of Defense to our mail. However, as you know Senator, we touch the lives of millions and millions of Americans. I'm not sure that the Defense Department gets the volume of mail that we do from individual citizens.

Senator PROXMIRE. One remark from the task force report may be useful to you. The report says "Too many responses are assigned for the Secretary's signature instead of direct reply. The HHS ratio of direct reply to Secretary's signature response is 1 to 1 and it probably should be about 5 to 1. A Secretary-signature reply averages 115 percent more time to complete than a direct reply."

Mr. SOPPER. It is true, Senator, that a letter that is being prepared for the Secretary's signature will take longer because it goes into the system and then has to come back to the Office of the Secretary and has to be reviewed by the Secretary.

Senator PROXMIRE. And you have a very high proportion of letters going through the Secretary.

Mr. SOPPER. That's true. The issue of secretarial signature versus direct reply mail is a policy call that generally reflects the operating style of the Secretary. If people write to the Secretary, it was former Secretary Schweiker's view—I have not discussed this matter with Secretary Heckler yet—that generally he should be the one to respond to that individual, whether it be a Member of Congress or a private citizen. You can have a perspective which may be operating in these other departments that even though a letter is addressed to the Secretary someone else can answer it.

I do want to emphasize that steps have been taken in the Department to speed up the response time on mail. One of the ways we are doing this, Senator, is to keep the letter in draft form until all edits and corrections are made. It used to be that each letter that was prepared for the Secretary's signature was initially prepared in final form and then if it was changed at a review level it would be again prepared in final. We are now using a draft system, and so letters are moving faster. The objective is to get the response time down to approximately 30 days.

MEDICARE/MEDICAID FRAUD, ABUSE, AND MISMANAGEMENT

Senator PROXMIRE. Mr. Kusserow, you plan to spend $8,729,000 next year and use a staff of 183 to combat fraud, waste, and abuse in the medicaid and medicare programs. Part of this funding and staffing would be used to conduct inspections which identify improper health care provider practices or weaknesses in program policies or implementation.

Last week I pointed out to the Administrator of the Health Care Financing Administration that your office had found that the more efficient procurement of pacemakers under the medicare program could result in an annual savings of $64 million. I also mentioned a General Accounting Office study that found savings could be made in the kidney dialysis program.

When I asked if the administration was going to implement these findings I was told that the new prospective payment system would require providers to police themselves and it would not be necessary to implement the findings.

If this is indeed the case, why can't we cut your budget in this area and devote the funds to more productive uses?

Mr. KUSSEROW. It would not be useful at this time, Senator, because many of the recommendations have not yet been implemented.

Senator PROXMIRE. Well, let me read the last part of my question again. When I asked if the administration was going to implement these findings I was told that the new prospective payment system would require providers to police themselves and it would not be necessary to implement the findings.

Mr. KUSSEROW. I think in any case where you have a system set up you are going to have to monitor that system. We are working very hard to be prepared to give almost immediate feedback as to what is going to occur after prospective reimbursement is initiated.

I think that you have to have—and I think it was the intent of the Congress—a body of auditors and independent reviewers of facts and evidence to report back to the Secretary and to the Congress actually as to how something is working.

So I think it is very important that we see just exactly how prospective reimbursement deals with these issues and report back to the Congress and to the Secretary. And I think that is our role and our statutory mission.

Senator PROXMIRE. You would need your staff for that purpose?

Mr. KUSSEROW. We're working very hard to internally redirect more resources into that area. We consider it vital to have more resources devoted proportionately to issues of the Health Care Financing Administration than had, heretofore, been the case. And so we are redirecting a major portion of our resources into that area, because it is a vital component of the health arena. We are seeing one of the most significant events since the advent of medicare itself, and we need to be there to give management immediate feedback as to what is going on out there so they can take corrective action wherever it is needed.

Senator PROXMIRE. Thank you very, very much, Mr. Chairman.

RELATIONSHIP OF REFORM 1988 TO GRACE COMMISSION REPORT

Mr. SOPPER. Mr. Chairman, if I may, with your indulgence I would like to respond a little bit further to Senator Proxmire's interest in the Grace Commission report in the context of another initiative that you may or may not be aware of, Senator. Reform 1988 is a major effort under the leadership of Deputy OMB Director Joe Wright to improve management processes and administrative systems in the Federal Government.

One of the things that Reform 1988 is trying to do is eliminate inefficient, duplicative systems in the Federal Government. Currently the Federal Government lacks uniformity in the way the various executive departments operate. It is sometimes not possible, even within one executive department, for various kinds of systems to talk to each other, much less to talk across executive departments. These systemic problems can be addressed by making use of modern software and ADP technology.

One of the things that we are doing at HHS, for example, which the committee has supported and the Congress has supported, is the development of a standard accounting system for the Department of Health and Human Services; that is, to have one accounting system instead of nine accounting systems.

The draft report of the commission recommended that we eliminate and terminate the development of that system.

So you have these kinds of competing perspectives, or I should say different perspectives, on how large institutions should be managed.

Now, I'm not sure that the task force report will maintain that recommendation when they are coming up with their final recommendations, because obviously the Reform 1988 initiative, which got started

subsequent to the President's private sector initiative, has established some different objectives and goals.

So, I think these two things have to be looked at in tandem. That is, the recommendations of the final task force report in light of the management perspective of the administration's Reform 1988 initiatives.

Another example that I would use to illustrate the need for a careful review of the task force recommendations with other competing management objectives is that the Congress has placed a high priority, in fact enacted a statutory requirement, that we have very aggressive audit resolution activities. Once the Inspector General or the General Accounting Office finds improper costs and recommends that disallowances be taken, the Congress established a 6-month time limit resolving those findings.

One of the things the commission report recommends be eliminated is that aggressive monitoring and follow-up activity.

So, again you have competing objectives here that I think have to be taken into account whenever we get that final task force report for comment.

Thank you, Mr. Chairman.

COMMUNICATION BETWEEN SUBCOMMITTEE AND HHS STAFFS

Senator WEICKER. I just have a few questions for you and those who accompany you.

Let me read to you what my staff wrote to me: "Senator, for your information the staff has had difficulty in dealing with the Department because they insist that all requests go through congressional affairs rather than the Budget Office. What this does is put us outside direct contact with those who know the budget, and that is why I suggest the attached question."

Mr. Sopper, which office has principal responsibility to the Secretary for the preparation and the presentation of the Department's budget, your office or congressional affairs? And does it also follow that your office is the principal spokesman for the Department and interacts directly with the Appropriations Committees on matters relating to the Department's budget?

Mr. SOPPER. The answer to the first question is that I am responsible, Mr. Chairman, for the preparation of the Department's budget, at least in terms of providing to the Secretary a recommended budget. It is ultimately the Secretary who decides what budget she wants to take to the President. So that responsibility is clearly mine, not that of congressional liaison.

The Secretary, however, has established a policy that relationships with the Congress, and that includes all the committees that deal with the Department, are the responsibility of the Assistant Secretary for Legislation. This is so that the Congress in terms of relating to the Department has one place that they can go to and expect to get service. That is not to say, however, that the Assistant Secretary for Legislation develops a response or excludes the relevant parts of the Department that the Congress needs to talk to in order to get information.

I am not aware that there is a problem for my office in furnishing information to the committee because of the Assistant Secretary for Legislation's role of coordinator for departmental congressional matters.

Senator WEICKER. Well, there is a problem. That's why I raised it.

Under your justification of appropriations estimates for the Committee on Appropriations, page 34, Office of the Budget, down toward the bottom of the page: "Provides primary support to the Secretary, the Under Secretary, and the Assistant Secretary for Management and Budget in presenting budget requests to the Office of Management and Budget and the congressional appropriations and budget committees."

What does that mean to you?

Mr. SOPPER. Well, that means to me that it is my office that does the work, does 99.9 percent of the work, or in some cases 100 percent of the work. That's what it means when it says provides primary support. The Office of Legislation does not have budget analysts or people who are expert in budget preparation and the intricate details of the Federal budget. I don't know that we would expect them to, Mr. Chairman. Their job is to be an interface with the congressional committees to make sure that you and the members of this subcommittee as well as the members of all the subcommittees that deal with this Department get the kind of service you expect.

Senator WEICKER. Mr. Secretary, I would suggest that on the matter of appropriations hearings there ought to be a direct relationship between your Department and the staff of this committee. I'm not requesting that a case for somebody in West Willington, Conn., be resolved. We're talking about the preparation of the budget. It is my job as it is your job. I don't know why we have to go through congressional relations, and obviously it has created difficulty for the staff. I can understand now why things get bogged down in the bureaucracy. That's the purpose of this committee; it's the purpose of your office. There is nothing very complicated about it. There is no reason why that shouldn't be direct.

Mr. SOPPER. With your permission, Mr. Chairman, I would like to suggest that the staff director and I sit down and discuss how we can deal with this problem and serve you and the rest of the members of this subcommittee.

EFFECTIVENESS OF HEALTH FINANCING PROGRAMS

Senator WEICKER. I agree. I'd appreciate it very much.

To the Inspector General. In your budget justification you describe a newly created component, the Office of Health Financing Integrity, that will maximize the effectiveness of programs in ways which do not restrict accessibility to beneficiaries of those programs but will reduce potential for fraud and abuse.

How do you propose to accomplish your task of reducing fraud and abuse without harming the legitimate beneficiary?

Mr. KUSSEROW. I think that the primary mission is to try to increase the efficiency of the flow of benefits to the beneficiaries even in a time

of budgetary constraint. The way we can do that most effectively is to find where in the pipeline that you have leakages due to fraud or abuse or mismanagement or otherwise inefficient utilization of resources. And that's what we intend to do. We will study the process as to actually how it is working and report back to the policymakers of our Department and to the Congress as to how it is working and how it may not be working the way it is supposed to. That's what these resources will be devoted to accomplishing.

Senator WEICKER. What kind of training will your investigators receive?

Mr. KUSSEROW. The Office of Health Financing Integrity are the transferred functions and staff from the Bureau of Quality Control, Health Care Financing Administration. These staffs have long and good experience and training in the area of dealing with the programs under the Health Care Financing Administration—medicare and medicaid.

In addition to that we are hiring specialized services. On my staff I have a surgeon who serves as medical adviser. We are also hiring a medical records librarian to give us a better understanding as to how accounts are going to be assigned in hospitals. We have hospital administrators. We have a wide variety of professional expertise in the health care industry and we are going to apply that against the health financing programs to see how it's operating and to test the system and report back to policymakers.

CIVIL RIGHTS POSITION SHIFT

Senator WEICKER. Ms. Dotson, in your budget justification you state that more emphasis is to be placed on voluntary compliance and outreach activities and less emphasis on compliance review and monitoring, and thus you will be shifting 44 positions, a 26-percent reduction in compliance review efforts, to the voluntary efforts, a 70-percent increase in that staff.

And you also state this policy shift reduces the need for legal services and you project eliminating 15 positions in that area.

Your projected caseload in 1984 is nearly 1,800, about the same as 1983. Internal regulations require that you follow up on any information indicating noncompliance.

Do you really expect to achieve your mandate, which is to enforce and implement the nondiscrimination statutes, by putting more people in a "please" and a "thank you" position rather than into enforcement?

Ms. DOTSON. Yes, Mr. Chairman. I would like to explain that. When we are talking about voluntary compliance, technical assistance or outreach we feel that this is indeed one means by which we accomplish implementation of the nondiscrimination provisions. The basic mission of our office is to enforce the nondiscrimination provisions of the laws for which HHS is responsible. One means of enforcement is the handling of complaints.

What we are saying is that we feel there are many means by which we can accomplish the basic goal, which is the implementation of non-

discrimination provisions, by doing more in the way of voluntary compliance or adopting what could be termed a preventive strategy. Our technical people, our equal opportunity specialists will be dealing with these problems before there is a point of polarization which would in itself inhibit or abrogate the need for the legal counsel.

COMPLAINT CLOSURES AND VOLUNTARY COMPLIANCE

Senator WEICKER. How many of the 1,800 complaints received in 1984 do you anticipate will be resolved by voluntary compliance?

Ms. DOTSON. I would anticipate that most of them would be resolved by voluntary compliance.

Senator WEICKER. How many did you have in 1983 and how many of those were settled by voluntary compliance?

Ms. DOTSON. I don't know. I'd have to supply that information for the record.

Senator WEICKER. I want a record of those complaints in fiscal 1981, 1982, and 1983 and exactly how they were resolved, if indeed they were resolved.

Ms. DOTSON. Yes, sir.

[The information follows:]

COMPLAINT CLOSURES FISCAL YEAR 1981 TO 1983

From fiscal year 1981 to the present 82.6 percent of the investigated and completed cases have been resolved voluntarily. Another 17 percent of the completed cases were closed due to consolidation with other compliance actions or because investigation indicated that OCR lacked jurisdiction in the case. To date, less than 1 percent of the complaints received in fiscal years 1981 through 1983 have required enforcement action. The following table provides data covering complaints received during the years in question:

	Fiscal year—		
	1981	1982	1983 (to 4/83)
Complaints received	1,704	1,234	565
Complaints closed	1,647	1,065	317
Investigated closures	693	284	33
Voluntary settlements	586	232	16
Enforcement	4		
Other investigated closures	103	52	17

CIVIL RIGHTS AND NEED FOR ENFORCEMENT

Senator WEICKER. Let me say this right now without in any way relating to actions of the Department, rather just making my observations in a general way. I believe at the present time the Civil Rights Commission seems to be a little bit anti, I guess is the best way to put it, since nothing formal was issued both in terms of the Department of Education and the Department of Justice in the matter of civil rights, and I have absolutely no indication whatsoever that the millennium has arrived here and that we can all just hope that the good side of human nature takes over.

Ms. DOTSON. I would completely agree with you, Mr. Chairman.

Senator WEICKER. If we are going to do our job in this area I think we had better have monitoring and I think we had better have enforcement.

Ms. DOTSON. What I was trying to say was that dealing with or reacting to a formal complaint of discrimination is one means of enforcement. It is not necessarily accurate that the universe of our potential beneficiaries would necessarily resort to the formal complaint mechanism to advise us of the problems. So, therefore, it is our feeling that we have to take the appropriate steps to communicate with that potential universe in order to find out and ascertain where the problems are and react to it as appropriate.

Senator WEICKER. As far as I'm concerned, Ms. Dotson, the universe tells me right at this point in our history that interest in civil rights is right down there. I'm not talking about the administration; I'm talking about the Nation as a whole. I don't think there is anybody that is involved in civil rights that wouldn't agree with that statement. I think the great danger now is going back, and I don't want to see that happen. I'm sure you don't either.

I have further questions for response to the record, both by the Chair and also other Senators on the committee.

Senator Proxmire, do you have any further questions?

EQUAL EMPLOYMENT OPPORTUNITY

Senator PROXMIRE. I just have two or three questions for Mr. Sopper and Ms. Dotson.

I would like to get some information on your equal opportunity program in the Department. Can you tell us what percentage of jobs at the GS–12 and above level are held by blacks and women?

Mr. SOPPER. You asked at the GS–12 level on up. I don't have it broken down that way, Senator. I can give it to you GS–13 through GS–15, and I can also give it to you GS–9 through GS–12.

Senator PROXMIRE. Give me both of those, and then give me the percentage that you employ altogether.

Mr. SOPPER. In terms of the total HHS work force, women occupied 55.2 percent of the GS–9 through GS–12 positions in December 1980, and 21.5 percent of the GS–13 through GS–15 positions. The percentage of women in these grade ranges increased in December 1981 by 0.8 percent and 0.9 percent, respectively. Two years later, in December 1982, women occupied 56.9 percent of the GS–9 through GS–12 positions and 22.6 percent of the GS–13 through GS–15 positions.

Senator PROXMIRE. Do I understand that correctly? What was the percentage you had at GS–9 and above?

Mr. SOPPER. Women were employed in 55.2 percent of the positions in the Department at the GS–9 through GS–12 level.

Senator PROXMIRE. That figure is astonishing to me, because it would imply that you have a lot of male secretaries.

Mr. SOPPER. Maybe this is another way to respond to your question. Sixty-three percent of HHS employees are women, while women represent 32.9 percent of the Federal work force and 42 percent of the civilian labor force. So 63 percent of our employees are women.

As of 1982, 34.2 percent of the HHS work force was composed of minority group members as compared to 23.5 percent of the Federal work force and 16.3 percent of the civilian labor force.

Senator PROXMIRE. What are your figures on minorities? You've given me them on women but not for the Department's proportion of your employees who are minorities.

Mr. SOPPER. In December 1980, HHS black employees occupied 15.4 percent of the GS–9 through GS–12 positions, and 9.5 percent of the GS–13 through GS–15 positions. That increased 0.6 percent and 0.1 percent respectively by December 1981 and 0.4 percent and 0.2 percent respectively in December 1982.

Senator PROXMIRE. So 25 percent of the blacks in that category and 75 percent of the women, is that about right?

Mr. SOPPER. Of the total positions in HHS, black employees occupied approximately 25 percent of the GS–9 through GS–15 grade range.

Senator PROXMIRE. And you said 75 percent of the women are in that grade range.

Mr. SOPPER. If you have no objection, Senator, I would like to give you a report for the record.

Senator PROXMIRE. I'd appreciate that. Frankly, in years in the past I've asked every department when I was chairman of this subcommittee, and independent offices and a number of agencies, and they did vary a lot. And it's one, though certainly not a perfect one, indication of the real conviction with respect to discrimination against women and minorities. But it's some indication, and I would appreciate getting that as comprehensively as possible.

You have given me part of it. What I would like to get from you is the proportion of women and the proportion of blacks in your Department related to the whole number of employees.

No. 2, the proportion that are in supervisory positions, that is GS–12 or above that are blacks, that are women related to the universe.

Also, how many blacks and women employed at GS–11 and below were promoted to supervisory jobs in the last fiscal year?

And finally, whether you have any minority employment goals within the Department, minority or women, and if so, what they are?

Mr. SOPPER. All right. We will give you a complete report on that.

[The information follows:]

MINORITIES

	Total	Women	Blacks
Proportion of women; proportion of blacks in the Department..	137,797	93,002	32,878
Percent		67.5	23.9
Proportion of women; proportion of blacks GS–12 and above..	28,758	8,477	3,457
Percent		29.5	12.0
Number of women; number of blacks GS–11 and below promoted last year		18,930	6,254

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. The balance of the questions that we have will be submitted to you for your response for the record.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

Questions Submitted by the Subcommittee

GDM Loss of Positions

Question: Your budget request for General Departmental Management indicates a net loss of 39 positions. When we take into account an increase in the number of positions for legal services (9) and Grant Payment System activities (6), the reduction in other areas if 54.

How do you intend to implement the reduction?

Answer: The staffing reductions made in General Departmental Management are a planned phased-in decrease implemented over several years.

Since FY 1982 we have eliminated 323 positions in response to changes in HHS programs, minor organizational changes, and the decreasing number of HHS employees for which support services are provided.

We have been able to implement these staffing reductions due to the:

- automation of various personnel and management functions;
- implementation of block grants, which reduce monitoring, reporting and evaluation workloads; and
- decrease in the number of HHS personnel requirements.

Since we began implementing these staffing reductions, we have essentially avoided significant adverse personnel actions. And we are confident that we will be able to continue to achieve the necessary FY 1984 staffing reductions through the use of attrition, thereby obviating the need for any reorganizations or reductions-in-force.

Field Management Staffing Reductions

Question: With a reduction of nearly 15% in field management, do you anticipate a RIF? What impact will this particular reduction have on field programs?

Answer: After a thorough management study was completed last spring, it was determined that a reorganization of field management activities in all regions would result in a more streamlined and efficient operation. Implementation of the findings of this study is essentially complete. As a result, we are able to effect these staffing reductions and still fulfill all essential workloads.

GDM Staffing Reduction Effects

Question: If these 1984 personnel reductions areapproved the net reduction since 1982 would be 323 -- or 8.5%. What impact have these reductions had?

Answer: The staffing reductions made in General Departmental Management have been a planned, phased-in decrease implemented in recent years. These staffing reductions have been possible for several reasons:

- o Departmental staffing as a whole has been decreasing as a result of various program changes; therefore, the need for support staff in GDM has decreased also;
- o Implementation of block grants has reduced workloads due to less monitoring, reporting and evaluation requirements;
- o Automation of various personnel and management functions have utilized existing staff more efficiently and freed up staff to concentrate on increased workloads in these and other areas; and
- o Additional operating efficiencies have also enabled us to use our staff resources more effectively.

As a result, we have been able to phase-in these staffing reductions as planned and without any negative impact on the operations of the Department's agencies.

EXECUTIVE DIRECTION POSITIONS

Question: If the 1984 request is enacted, executive direction will have incurred a net reduction of 144 positions since FY 1981. However, I found it interesting to note that, while most offices have incurred staffing reductions, there has been no change in the position levels for the Assistant Secretary for Legislation or for the Office of the General Counsel. While the overall reduction has been ten percent, can you tell us why these offices should be spared?

Answer: Staffing of the General Counsel function is maintained, while nearly all other Executive Direction activities are reduced, because effective management of workloads from Continuing Disability Investigations, Bellmon Reviews, and Civil Money Penalty actions requires continuing direction and policy guidance.

The reason that these two offices have not had staffing reductions since FY 1981 is that the workloads in those offices has increased over the past three years. In the Office of the Assistant Secretary for Legislation, for example, since 1981, this Administration has launched several major legislative at program intiatives, including significant reforms in health care financing, amendments to the AFDC program, new block grants, a health promotion program, and a strengthening of the Social Security system. These initiatives place extensive work demands on our legislative and congressional relations staff to effectively coordinate preparations for Congressional hearings, and to provide comprehensive liaison services to individual members of Congress.

Similarly, in the Office of General Counsel, recent legislation enacted by the Congress, including the Social Security Disability Amendments of 1980, the Omnibus Reconciliation Act of 1981, and the Tax Equity and Fiscal Responsibility Act of 1982, include

major statutory changes which increase the need for legal advice and legal services in the Department. For example under the Social Security Amendments of 1980, the Department is required to review periodically the disability status of each recipient of disability benefits under the Social Security Act. As a result of these reviews, we expect over 4,000 new court cases in each of FY 1983 and FY 1984. To adequately defend the government's position in these cases, we need to strengthen our legal services staff. Proper defense of these cases will result in millions of dollars in avoided benefit payments. The 1980 Disability Amendments also require the Department to implement a plan to review decisions of Administrative Law Judges which are favorable to the claimant. These reviews, called "Bellmon reviews," are expected to result in over 1,000 new court cases in each of FY 1983 and FY 1984. Failure to properly represent the Administration's position in these cases could result in the loss of millions of dollars in avoided benefit payments.

Question: And in addition, the Office of Public Affairs has actually increased by three positions, and the Office of Management and Budget has increased over this period of time. Why have the staffs for these offices actually increased in the intervening period?

Answer: The Office of Public Affairs is not increasing by three positions from FY 1983 to FY 1984 in comparable terms. The Justification includes 49 positions in each of these years. An apparent increase of three positions will however result from a comparison of the FY 1983 budget request (which included only 46 positions) with the FY 1984 request (which includes 49 positions in both FY 1983 and FY 1984). But this comparison lacks an adjustment necessary to reflect the transfer of three positions associated with "Freedom of Information" workloads. The FY 1984 request for Public Affairs includes two positions transferred from the Public Health Service and one position transferred from the Health Care Financing Administration to perform "Freedom of Information" work. In the FY 1984 Justification the current year and past year data are portrayed as if the transfer was in effect during all three years so that year-to-year comparisons will reflect only "true" increases and decreases, not transfers which have no net effect on Departmental staffing.

The staffing level is not reduced in FY 1984 because the Office of the Assistant Secretary for Public Affairs (ASPA) will continue to assume greater responsibility in the management of public affairs activities throughout HHS in FY 1984. These efforts reduce costs, avoid duplication of effort and improve the quality in all public affairs products of the Department.

This office has been responsible for budget savings totaling $16.2 million in the past year from:

	Savings
-- elimination of overlapping publications and periodicals.....	$ 7.2
-- termination and consolidation of duplicative clearinghouse.....	7.4
-- reduction in audiovisual activities.....	.4
-- increased cost recovery through publication user fees.....	1.0
-- increased collection of fees for FOI Act requests.....	.2
Total	$ 16.2

In the budget year, we are implementing a number of management initiatives—eliminating unnecessary spending on periodicals, pamphlets and audiovisuals, monitoring of publications control system, inventory of recurring publications, increased cost recovery through user fees, and review of selected HHS clearinghouses and information centers—without additional resources. At the same time we are reducing our non-permanent staff year equivalents by more than 10 percent and consolidating workloads to accommodate this loss.

The six new positions requested for the Office of Management and Budget are for the Payment Management System which will enable the Department to accelerate conversion of the grantee payment mechanism from many Federal Reserve Bank letters of credit to computerized electronic fund transfers through the Treasury Financial Communications System (TFCS). In FY 1984, these actions are expected to yield HHS outlay deferrals of $101 million and Federal interest savings of $8.2 million.

LEGAL SERVICES POSITIONS

Question: Legal Services positions requested and provided for FY 1983 are 58 less than FY 1982. Now for FY 1984 you are requesting an increase of 9 positions. You state in your budget justification that this request is due to an increase in workloads resulting from laws enacted in the past 3 years. Don't you think you might have been more careful in your predictions for FY 1983? Could you explain this apparent contradiction in staffing requests?

Answer: The Office of the General Counsel could not reasonably predict in 1981 (when the 1983 budget was prepared) the rapid surge in civil actions resulting from the enactment of P.L. 96-265, (the Social Security Disability Amendments of 1980). Estimates at that time were based on projections of workloads which have since proven to be understated. The 1984 estimate is based on actual workload increases in FY 1982 (for the full year) and for FY 1983 (for part of the year) resulting from these Continuing Disability Investigations and Bellmon reviews. We believe that the estimates made in the FY 1984 budget request will prove accurate and will be sufficient to meet the increase in legal cases associated with the Continuing Disability Investigations and Bellmon reviews.

Question: In your budget request, I note that there are two prinicipal requests for legal activity functions. One is for $2.5 million for the General Counsel. The other for $22.3 million for the Legal Services staff—which is under the direct control of the General Counsel. Why have you separated these budget requests?

Answer: The legal activity request was separated into General Counsel and Legal Services to differentiate those legal efforts devoted to staff support for the Secretary's executive direction responsibilities (General Counsel) from those legal efforts devoted to operations of assigned programs (Legal Services). This differentiation between executive direction and operations is made in each of the General Departmental Management functions. This distinction is made in order to provide the Congress with an accurate description of these two different functions of the Office of General Counsel.

EEO BACKLOG

Question: You are requesting an additional $400,000 for the Office of Personnel to pay for 160 EEO investigations. I have several concerns in this area. First of all, why is there a backlog of 160 cases?

Answer: Recently, the volume of cases received and accepted for investigation has exceeded our staff capability to perform this work. I would like to point out that some backlog or more precisely "work in progress" is essential to the efficient operation of any investigatory type operation.

Question: What is the total projected EEO case-load in FY 1984 and how large is the projected backlog?

Answer: Based on the recent volume of cases, we can expect receiving up to 500-550 new cases requiring investigation during FY 1984. In addition, an inventory of work in progress will be carried forward from 1983 into 1984. Historical data indicates that 16 investigators will complete approximately 350 investigations in a year. Therefore, unless we receive the $400,000 requested for contracting out the task of 160 EEO investigations, we will close out the year with a backlog in the area of 150-200 cases. This outcome is unacceptable because EEOC regulations stupilate that complaint investigations must be completed with 180 days.

Question: Why did this backlog accummulate and why have you decided to contract out the investigations?

Answer: Since predicting the number of complaints received and requiring investigation is inexact during changing employment situations, good management procedure dictate the permanent staffing of this office at a level sufficient to handle the long term projected workload and to utilize contractual investigators to perform variant workloads. This flexibility offered by contracting has enabled HHS to deal with the overloads occasioned by fluctuating complaint receipts while not incurring the regularly recurring costs associated with increased permanent in-house staffing.

Question: How many EEO investigators will you have in 1984 as opposed to 1980 and 1981?

Answer: There will be 16 investigators in 1984 as opposed to 22 in 1980 and 19 in 1981.

Question: Assumming we approve this request for external help, will you have sufficient resources to remain current with your projected workload?

Answer: Our budget request is sufficient to handle all estimated EEO complaint investigations in FY 1984 in a timely fashion.

DEPARTMENTAL CONTRACT INFORMATION SYSTEM

Question: What is the Departmental Contract Information System and why does the Department want to expand it?

Answer: The Departmental Contract Information System is a computer based system intended to provide data on the Department's procurement activities, satisfy Federal statutory or administrative reporting requirements and respond to Congressional and public inquiries. The system was designed in the mid-1970's and does not meet the management needs of today in that:

-- It does not contrain the pre and post-award information necessary to effectively manage and oversee the procurement function.

-- It is dependent on separate and uncoordinated data systems of each of the Operating Divisions and Staff Divisions. This decentralized configuration results in incompatible data, haphazard documentation, duplication of effort and disparities in the quality and content of feeder systems, and excessive costs.

The proposed changes to the Department Contract Information System sill eliminate these problems. It will expand the data base, increase the timeliness and accuracy of data, and integrate the Department Contract Information System with other Departmental contract information systems to make the data more useful to procurement managers at all levels and make the system more cost effecive. The revised Department Contract Information System will involve a centrally managed data base containing the appropriate data to meet the needs of all procurement managers, and allow the Operating Divisions and Staff Divisions to input and retrieve data directly using on-line computer terminals or remote entry. It will eliminate the need for the amny separate and redundant contract information systems in the Operating Divisions, resulting in anmual savings of over $2 million and elminiate the need for the design, development and implementation of additional Operating Division contract information systems in the future.

DEBT COLLECTION

Question: What are the Department's debt collection goals for this fiscal year and next?

Answer: Our goal is to collect $1.4 billion in the current fiscal year and $1.6 billion in fiscal year 1984.

Question: Have you been satisfied with past performances in this area?

Answer: In fiscal year 1982, the Department collected $438.7 million more of its outstanding debt than was collected during fiscal year 1981. We believe that debt collection has been an important concern of management, and we intend to see that the aggressive program already begun in HHS is continued.

Question: Please describe how you plan to improve performance in this area?

Answer: A number of actions are being taken to improve our debt collection. The Department is piloting use of commercial collection agencies to collect debts owed the Public Health Service, if in-house efforts are unsuccessful. We are charging interest on all debts not repaid within 30 days after notice that the debt is due, except overdue debts owed the Social Security Administration. Procedures are being developed to notify credit bureaus of delinquent debtors under those programs having such authority under the Debt Collection Act of 1982. Procedures are also being developed to collect all debts due the government by Departmental employees through a salary offset mechanism. Internal controls are being improved to minimize overpayments to beneficiaries.

Question: How many dollars remain uncollected as of September 30, 1982. Please provide the Committee with the outstanding debt for each account?

Answer: As of September 30, 1982, the Department was owed $3,379 million. The following table shows the outstanding debt for each account.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
UNCOLLECTED BALANCE AS OF SEPTEMBER 30, 1982
($ in THOUSANDS)

	Account(s)	Balance Owed
Social Security Administration		
Old Age Survivors Insurance	75-20X8006	$ 742,066
Disability Insurance	75-20X8007	391,893
Black Lung	75-0409	20,800
Supplemental Security Income (benefit Overpayments)	75X0406	1,105,912
Supplemental Security Income (State Supplementation)	75-0406	18,658
Assistance Payments Appropriation	75-0412	23
Refugee Assistance	75-0473	5
Collection of Past Due Support of Federal Tax Refunds	75X6234	3,125

	Account(s)	Balance Owed
Fees & Other Charges for Other Services	752419.2	11
Payment from State for Receipt of Child Support	75X5734	1
Limitations on Administrative Expenses	75-8704	765
U.S. Repatriate	75X2430	386
Audit Disallowances	Not Available	37,807
Subtotal		2.321,452
Public Health Service		
Alcohol Drug Abuse and Mental Health Administration	75-1300,1361	4,406
Center for Disease Control	75-0943	541
Food and Drug Administration	75-0606, 75X4309	174
Health Resources Administration	75-0712, 2970	48,000
Medical Facilities Construction Loan Guarantee	75X4430	29,398
Health Services Administration	Not Available	756,077
Nurse Training Fund	75X4306	9,622
Health Professions Education Fund	75X4307	20,378
Health Professions Graduate Student Loan Insurance	75X4305	378
National Institutes of Health	Not Available	3,442
Office of Assistant Secretary for Health	75-1101, 3903	77
Health Maintenance Organization	75X4435	34,697
Audit Disallowances	Not Available	9,644
Subtotal		916,834
Health Care Financing Administration		
Program Management	75X30511	49
Audit Disallowances	Not Available	100,296
Subtotal		100,345
Office of Secretary		
Departmental Management	75-0120	516
Working Capital Fund	75X4503	7
Audit Disallowances	Not Available	6,428
Subtotal		6,951
Human Development Services		
General Fund	75-1636	72
Audit Disallowances	Not Available	34,081
Subtotal		34,153
Total		$3,379,735

OTHER SERVICES OBJECT CLASS

Question: In the Departmental Management object classification you are requesting an increase of $3.2 million in FY '84 for "Other Services." Please tell us specifically what these "Other Services" are and their expected costs.

Answer: The object class of "Other Services" is comprised of such items as: ADP services and contracts, repairs and alterations to buildings; miscellaneous contractual services such as training, management information/investigations, or research and development; and maintenance agreements and repairs of office machines.

The net increase of $3.2 million in this object class results from the following:

Built-ins:

- a 5.1% increase to cover the cost of inflation for ADP services and contracts ($256,000)
- a 2.9% increase of $10,000 for consultant services to partially offset the cost of inflation;
- a 5.1% increase in other services (such as training, repairs and contracts) to offset the cost of inflation ($292,000);
- the annualization of special projects approved for FY 1983 and continuing into FY 1984 ($2,459,000);
- a built-indecrease of $332,000 for non-recurring costs of special projects approved for FY 1983 and completed that year; and

Program:

- a net program increase of $543,000 to support a portion of the increased costs of the four special projects requested in FY 1984.

OTHER RENTS, COMMUNICATIONS AND UTILITIES OBJECT CLASS

Question: In the same object classification you are requesting $1.7 million for rents, communications and utilities. Please expand your description of this classification. How does it relate to the SLUC charges?

Answer: The object classification 23.2 (other rents, communications and utilities) is comprised of: rental payments for office machines and equipment, telephone equipment and photocopy machines; rental of ADP equipment; communication services such as postage, teletype machines and the Federal Telecommunications System; and charges for utility services such as heat, light power, water, gas and electricity not already included in SLUC payments.

The $1.7 million increase in this object classification breaks out as follows:

	($ in thousands)
o built-ins:	
Phones: voice	$182
data	5
ADP equipment	57
Postal services	166
Other office equipment	3
Other utilities	60
	$473
o program increases/modifications	
Phone: telecommunication for SAS	160
alterations/modifications due to staff changes	910
ADP equipment	150
	$1,220
Total increase	$1,693

Object class 23.2 includes rentals for items other-than payments for space rentals to the General Services Administration (GSA). Payments for space rental to GSA--Standard Level User Charge (SLUC) are displayed in object class 23.1.

Question: Your budget justifications (Page 38) indicate that you reviewed 53 consulting services contract requests valued at $100,000 or more.

Were these consulting contracts for the entire DHHS?

Answer: Yes, all but one of our operating divisions submitted at least one contract over $100,000 which the Office of the Secretary staff reviewed. The Public Health Service had the largest number of such contracts: 44. The Health Care Financing Administration did not submit any consulting services contracts over the $100,000 threshold.

Question: How many consulting contracts fell below the $100,000 level? Who is responsible for reviewing those?

Answer: During Fiscal Year 1982, the Department awarded 493 consulting contracts under $100,000 for a total amount of approximately $8,400,000.

Responsibilities for review and approval of consulting services contracts under $100,000 are set forth in the Department's General Administration Manual. The Department's individual operating divisions have procedures for processing contracts with estimated costs under the $100,000 threshold. The type and dollar amount of the contract determines who actually reviews it:

1. Noncompetitive Contract

If over $10,000, the Operating Division or Staff Division head or that individual's principal deputy, as delegated without further redelegation, must review. If under $10,000, the

contract is treated as a purchase order which any responsible staff office delegate, except the project officer, may approve.

2. Competitive Contract less than $25,000

The Operating Division or Staff Division head or that individual's delegatee down to one level below that of principal deputy must review. (If under $10,000, the contract is treated as a purchase order.)

3. Competitive Contract $25,000 or more

Operating Division or Staff Division head or that individual's principal deputy, as a delegate, without further redelegation must review.

Question: What is the basis and/or your methodology used in making your determination of approval or disapproval?

Answer: In our review of proposed consulting services contracts, we analyze such factors as:

o the importance of proposed effort as related to program objectives and goals;

o whether the effort is duplicative of other similar efforts already underway;

o whether the tasks in the proposed contract are complete and/or appropriate;

o whether the program needs to contract for such service or has the capability to conduct the effort "in-house";

o whether the estimated costs are reasonable; and

o whether the proposal meets the requirements of other procurement procedures.

Question: Who is responsible for the evaluation of the services received from the consultant/contractor?

Answer: The project office establishes criteria on which a deliverable product can be judged. Acceptance criteria for deliverables are normally stated in a description of the deliverable products or in a separate contract action. The project office assesses and accepts the contract deliverable based on the acceptance criteria.

CONSULTANT SERVICES

Question: While consultants certainly have their proper place, the Department has in the past, received some criticism for its expenditures in this area. Why is no discussion contained, or mention made, of a specific, or estimated amount which is anticipated to be expended for consultant services by the Department?

Answer: In past years, the Department of Health and Human Services included estimates of consultant services expenditures as a part of its Congressional justification. This was included in response to requests of the Congressional Appropriations Subcommittee. For the FY 1984 Congressional budget process, however, in order to reduce the bulk of the DHHS justifications, the Appropriations Subcommittee indicated that it would not be necessary for DHHS to include the consultant services estimates in its justifications. Instead, a special report on consultant services estimates could be sent separately to the Subcommittees. This report was sent to the Appropriations Subcommittees in March 1983.

Question: What entity within the Department is charged with ensuring that we get what we pay for from consulting services?

Answer: If the contractor fails to deliver acceptable products or otherwise perform under the contract, the contracting officer is responsible to determine, with the advice of the program officer and other appropriate technical, cost, and legal advisers, what recourse is appropriate, and to take that action on behalf of the Government.

Question: How much was spent for consulting services in fiscal years 1982 and thus far in 1983?

Answer: Consulting services obligations in FY 1982 totaled $8,226,000. Of the $8,226,000, $8,000,000 was made available to the Office of the Assistant Secretary for Planning and Evaluation through reimbursable agreements with the Public Health Service and the Office of Human Development Services under evaluation set-aside authorities. Thus far in FY 1983, $5,969,000 has been committed for consulting services. The annual estimate for FY 1983 is $8,444,000, of which $8,100,000 is evaluation set-aside funds.

Question: How much do you anticipate will be expended for consultant services, excluding those to be used by the Office of the Inspector General, for fiscal year 1984?

Answer: We anticipate that in FY 1984 General Departmental Management (GDM) will obligate $8,450,000 for consultant services, the Office for Civil Rights (OCR) will obligate $175,000 and Policy Research will obligate no funds for consultant services.

A breakout of these funds between appropriated and non-appropriated is detailed below:

	GDM	OCR	Policy Research	Total
Appropriated.....	$350,000	$175,000	---	$425,000
Non-appropriated..	$8,100,000	---	---	$8,100,000
Total.....	$8,450,000	$175,000	---	$8,525,000

CASH MANAGEMENT - DELAY-OF-DRAWDOWN

Question: What is the "Delay-of-Drawdown Procedure" and why is it used?

Answer: The delay-of-drawdown procedure is an advance funding letter of credit method which requires the States to draw Federal cash when State checks or warrants are cleared by the State's commercial bank, rather than draw funds on or before the dates when checks are issued. Under the delay-of-drawdown procedure, the cash "float" is removed from the banking system, thus preventing loss of interest savings to Treasury. The procedure is used to defer Federal outlays, which in turn, saves Federal interest costs.

Question: How long has the Department been using this procedure with the States? How many States are using the procedure? Is it successful?

Answer: The Department began implementing a delay-of-drawdown procedure in fiscal year 1980 for financing the Public Assistance programs (Aid to Families with Dependent Children (AFDC) and Medicaid). The procedure was initially implemented in thirty-two States over a three year period. Subsequently, three States (Illinois, Indiana, and Missouri) have unilaterally withdrawn from the procedure leaving us with twenty-nine States currently operating under the delay-of-drawdown.

The successfulness of the procedure has been measured in these terms.

- From 1980 to 1982, the procedure produced an estimated $412 million in outlay deferrals.

- As a result, Treasury's borrowing costs have been reduced by $56 million based on a 13.0% per annum interest rate (the Current Value of Funds rate to Treasury for the quarter ending June 30, 1983).

Question: I understand that there is substantial controversy surrounding the procedure in some States. What is the problem causing this controversy?

Answer: Some States present the argument that under the delay-of-drawdown procedure, they are required to "front-end" the Federal share of payments with State cash because under their State Statutes and/or Constitution they are required to have cash in their treasury before they can issue a check or a warrant. We have asked those States to work with their State legislatures to remove those restrictions and have offered to tailor the delay-of-drawdown procedure to meet their requirements. We have asked the States to recognize that under Federal Treasury regulations, the letter of credit is equivalent to cash on hand and guarantees that cash will be in the State treasury when their checks or warrants are presented for payment.

Question: How many States are involved in this controversy?

Answer: Of the twenty-six States that have the restriction requiring them to have cash in their treasury before issuing a check or a warrant, seven are currently operating under the delay-of-drawdown procedure, three are tentatively committed to become operational in FY 1983, three have suspended the use of the delay-of-drawdown procedure pending resolution of some internal problems, and thirteen have declined to implement the procedure. To date, there have been no complaints about shortages of Federal cash from any State operating under the delay-of-drawdown.

Question: How are you resolving the difficulties?

Answer: At the present time, there are ongoing negotiations between Federal officials (Office of Management and Budget, Department of Treasury) and representatives of State governments to develop equitable and more standardized cash management policies to be used in the financing of the Federal assistance programs. In support of this cooperative effort, HHS has advised the Office of Management and Budget that it will hold in abeyance the implementation of the delay-of-drawdown procedures in States not now utilizing it.

Question: Are you going to implement the delay-of-drawdown procedure in the face of continuing opposition?

Answer: HHS' use of the delay-of-drawdown procedure has been effective in deferring over $400 million in outlays and in saving substantial interest costs of over $50 million. We are aware that the Congress has expressed concern that the Federal government lacks a fair, consistent cash mangement policy in its dealings with the States. We have advised the Office of Management and Budget that we will hold in abeyance any further implementation of the delay-of-drawdown procedure in States not now utilizing it, pending joint Federal-State agreement on more equitable and standardized cash management policies in financing Federal assistance programs. We hope that this agreement between the States and the Federal government can be reached in 60 days or less. We will then resume our activity with the States to implement the policies set forth by the agreement.

PAY RAISE

Question: We notice the absence of a request for additional funding in FY '83 for increased FY '83 cost. How did you absorb the $6.8 million pay increase?

Answer: We will be able to absorb all pay raise and pay raise related costs in FY 1983 as a result of Congressional action freezing rental rates for payments to the General Services Administration (GSA) at the FY 1982 level.

In FY 1984, all of the increased pay costs have been included in the budget request.

ON-BOARD PERSONNEL

Question: How does your 1983 on-board strength compare to your authorized personnel ceiling of 3,507? For the record, please provide details.

Answer: As of March 19, 1983 the General Departmental Management (GDM) appropriation had 3,197 full-time permanent on-board personnel.

The total staffyear ceiling for full-time permanent employees for FY 1983 is 3,358 (as compared to the authorized full-time permanent position level of 3,507). This staffyear ceiling was developed based on a normal vacancy rate (lapse rate) of approximately 4%.

The historical 4% vacancy rate is attributable essentially to the normal turnover ti e involved in filling vacancies as they occur.

Another factor contributing to what appears to be a somewhat high lapse rate is that the Office of General Counsel (OGC) normally recruits and hires law students graduating in the Spring. This cyclical pattern of hiring is reflected in the current high level of vacancies in OGC; however, by July it is anticipated that many, if not all, of these vacancies will be filled.

SPACE RENTAL INCREASE

Question: We understand that the DHHS does not set the Standard Level User Charges (SLUC) that are requested in your budget. However, wouldn't you agree that a 92% increase from $11,729,000 to $22,540,000 is excessive?

Answer: Yes, I agree it looks that way.

Question: Did you question it?

Answer: Yes, I did question it.

Question: What was the response to your question?

Answer: The response relates to the system GSA has for managing office space and for billing Federal agencies that use that space. SLUC rates are established by GSA in accordance with the provisions of P.L. 92-313. They are based upon Fair Annual Rental (FAR) appraisals conducted on a 3-year cycle and adjusted for anticipated changes in the rental market in the intervening years.

Because of the Congressional freeze on FY 1983 SLUC rates at the FY 1982 level, the FY 1984 budget must reflect an increase in the commercial market over a 2-year period.

SMALL BUSINESS INNOVATION RESEARCH

Question: Congress recently passed the Small Business Innovation Research legislation to ensure that small businesses receive a guaranteed share of Federal research and development funds. Describe the progress that HHS has made in implementing this legislation?

Answer: The Department is making satisfactory progress in implementing the legislation. We estimate our Small Business Innovation Research (SBIR) program to be approximately $6.6 million for FY 83. Accomplishments to date include:

Consolidating biomedical research, health services research, and social services research into separate SBIR solicitations. The first two to be managed by the Public Health Service and the latter by the Office of Human Development Services.

Designating the Office of Small and Disadvantaged Business Utilization as the Departmental Coordinator for the program.

Issuing an Omnibus SBIR solicitation by the Public Health Service (PHS) on January 10, 1983. The PHS accounts for approximately 97 percent ($6.4 million) of the Department's SBIR activity. The receipt date for grant applications is May 1, 1983. Over 25,000 small businesses have been informed of the availability of the PHS solicitation. Over 5,000 solicitation have been mailed to interested small businesses.

Hosting a conference for small businesses interested in participating in the Department's SBIR program. Over 25,000 small businesses were informed of the SBIR conference; approximately 400 attended.

Making plans to issue the social services SBIR solicitation by May 1, 1983. The receipt date for applications for this solicitation will be July 1, 1983.

Participating in a number of conferences sponsored by private industry, universities, and the National Science Foundation. Individual counseling has been provided to hundreds of small businesses interested in participating in the Department's SBIR program.

We are pleased with the progress we have made so far. We are making determined efforts to afford small businesses the maximum opportunity to participate in all of the Department's research programs. We are hopeful that capable small businesses will respond to our efforts.

Question: Can you review for us what kinds of grants are made under this program?

Answer: We expect to award grants and cooperative agreements to successful applicants who compete for SBIR awards. We will make awards in three broad categories:

1) biomedical research,

2) health services research, and

3) social services research

Question: Can you provide us with a list of the grants made in this program for FY 83?

Answer: SBIR awards for FY 83 have not yet been awarded. However, the list of research topics which were included in our SBIR program solicitations follows:

SOCIAL SERVICES RESEARCH TOPICS

1. Techniques and products to reduce the cost of health and human services.

2. Techniques and products to improve the management and reduce the administrative costs of health and human services.

3. Techniques and products to improve client information on available health and human services.

4. Techniques and products to improve the ability of the elderly and disabled to live productively at home.

BIOMEDICAL AND HEALTH SERVICES RESEARCH TOPICS

1. Biomedical Research and Clinical Medicine: geriatric medicine; physiology of aging; molecular and cellular basis of aging

2. Behavioral Sciences Research: psychological, cultural, social and economic factors that affect aging and the elderly

3. Immunology, Allergic and Immunologic Diseases

4. Microbiology and Infectious Diseases

5. Arthritis, Musculoskeletal and Skin Diseases

6. Diabetes, Endocrinology and Metabolic Diseases

7. Digestive Diseases and Nutrition

8. Kidney, Urologic and Hematologic Diseases

9. Cancer Biology and Diagnosis: tumor biology; cancer immunology; cancer diagnosis

10. Cancer Cause and Prevention: chemical carcinogenesis; viral carcinogenesis; epidemiological studies of cancer

11. Cancer Treatment: cancer and nutrition; clinical treatment; biochemistry and pharmarcology; radiation research; biological response modifiers

12. Cancer Resources and Community Activities: screening; smoking, diet and other life-style factors; chemoprevention; epidemiological studies

13. Population Research: reproductive science; contraceptive development; contraceptive evaluation; population dynamics

14. Research for Mothers and Children: clinical nutrition and early development; mental retardation; child and adolescent development

15. Dental Research

    a. Caries

    b. Periodontal Diseases

    c. Craniofacial Anomalies

    d. Restorative Materials

    e. Pain Control and Behavioral Studies

    f. Soft Tissue Stomatology and Nutrition

16. Characterization of Environmental Health Hazards

17. Biological Response to Environmental Health Hazards

18. Applied Toxicological Research and Testing

19. Biometry and Risk Assessment

20. Eye Research

    a. Retinal and Choroidal Diseases

    b. Corneal Diseases

    c. Cataract

    d. Glaucoma

    e. Strabismus, Amblyopia and Visual Processing

    f. Low Vision and Rehabilitation

21. Cellular and Molecular Basis of Disease

22. Genetics
23. Pharmacological Sciencies
24. Physiology and Biomedical Engineering
25. Arteriosclerosis
26. Hypertension
27. Cerebrovascular Diseases
28. Coronary Heart Disease
29. Peripheral Vascular Disease
30. Congenital and Rheumatic Heart Disease
31. Cardiomyopathies
32. Arrhythmias
33. Heart Failure and Shock
34. Circulatory Assistance
35. Structure and Function of the Lung
36. Pediatric Pulmonary Diseases
37. Chronic Obstructive Lung Diseases
38. Fibrotic and Immunologic Interstitial Lung Diseases
39. Pulmonary Vascular Diseases
40. Respiratory Failure
41. Blood Diseases Including Bleeding and Clotting Disorders
42. Red Blood Cell Disorders
43. Sickle Cell Disease
44. Cooley's Anemia
45. Aplastic Anemias and Related Disorders
46. Isolation, Preservation and Therapeutic Use of Blood Products
47. Efficient Utiliztion of National Blood Resources
48. Communicative Disorders: speech, hearing, language, equilibrium and the special senses
49. Fundamental Neurosciences: nerve structure and function; learning in simple systems

50. Stroke and Trauma

51. Convulsive, Developmental and Neuromuscular Disorders

52. Demyelinating, Atrophic and Dementing Disorders

53. Digital Technology, Engineering and Information Technology Applications to Biomedical Research

54. Nuclear Magnetic Resonance

55. Electron Microscopy

56. Biochemical Kinetics

57. Etiology, Pathogenesis and Control of Laboratory Animal Diseases

58. Environmental Requirements of Laboratory Animals

59. Biomedical Research Methods Employing Lower Organisms, Tissues/Cells in Culture or Mathematical and Computer Simulations

60. Pharmacologic Agents for Treatment of Alcoholism

61. Technologies and Procedures for Early Detection of Alcoholism

62. Instrumentation for Measurement (especially non-invasive) of Blood Alcohol Concentration

63. Software Programs and Appropriate Hardware for Computerized Educational Audiovisual Aids (Alcoholism)

64. Animal Models for Study of Alcoholism

65. Assays for Cannabinoids

66. Technology/Techniques for Prevention Strategies Targeted at Adolescents

67. Methods for Assessment of Prevention Prorams

68. Measurement of Drug-Induced Impairment

69. Mental Health

    a. Software and statistical Packages to Povide Specialized Data Prcessing and Analysis Programs

    b. Assessment of Clinical Applications of Computers

    c. Software to Process Routine Clinical Operations of Mental Health Facilities

    d. Improvements in Mass Spectrometry (e.g., ion detector/amplifiers, electron emitting filaments)

e. Neurophysiology

f. Physiological Monitoring Devices and Methods

g. Two-Dimensional Electrophoresis

h. Improvements in Tomography: Instrumentation and Chemistry

i. Nuclear Magnetic Resonance

j. Software for Analysis of Data Obtained from NMR Imaging Techniques

k. Genetic Probes

l. Monoclonal Antibodies for Neural Antigens

m. Psychometric Instruments That could be Standardized for Assessing Psychotropic Drug Effects in Geriatric Patients

n. Devices to Assist in Drug Management Among Aged Patients

70. Research on and Development of Methods/Approaches for Problems in the Following Areas of Occupational Safety and Health:

a. Occupational Lung Disease

b. Occupational Musculoskeletal Injuries

c. Occupational Cancer

d. Occupational Traumatic Injuries

e. Occupational Cardiovascular Disease

f. Occupational Reproductive System Problems

g. Occupational Neurotoxic Disease

h. Occupational Noise Induced Hearing Loss

i. Occupational Skin Disease

j. Occupational Psychological Disorders

k. Control Technology Research

l. Respirator Research

71. New methods for assessing the safety and efficacy of medical devices

72. Effects of ultrasound radiation exposure on membranes

73. New technology in radiology (digital radiology or teleradiology)

74. A seriological marker test for identifying hepatitis Type Non A or Non B antigens

75. Development of new analytical methodology for conducting bioavailability and bioequivalence drug studies

76. New methods of assessing the safety and efficacy of drugs

77. Minor use and minor species animal drugs

78. Reviews and Synthesis of Information on Innovative Applications of Quality Enhancing and Cost Saving Technology in Health Care Delivery in the Following areas:

    a. Innovative Medical Information Systems

    b. Capital Substitutes for Labor Intensive Procedure

    c. Diagnostic and Therapeutic Protocols

79. Factors Influencing Adolescent Sexual Behavior

80. Why Adoption Rates have Declined; Effective Strategies for Establishing Adoption as a Viable Alternative

81. Assessing Services and Policies to Aid Pregnant and Parenting Adolescents and Their Families

Question: Please provide us with a description of the methods used to evaluate each grant proposal?

Answer: Procedures which will be used to evaluate applications submitted in response to our social service research program are as follows:

Review Process - Applications will be initially screened to determine responsiveness to the program solicitation. Those found to be non-responsive will be returned to the applicant. Applications considered responsive will be reviewed competitively and evaluated by a panel of experts for technical merit. Senior officials of the appropriate funding agency or office will make the decision whether or not to fund a particular application. Funding criteria include such factors as : (1) ratings resulting from the technical evaluation process; (2) program relevance; (3) priorities of the SBIR Program (e.g., demonstration of prosepctive non-federal capital commitments); (4) program balance; and (5) availability of funds.

Technical Evaluation Criteria - In considering the technical merit of each application, the following factors will be assessed:

1. The soundness and technical merit of the proposed project, the anticipated products that may be derived from the

effort, and the adequacy of the proposed effort; given the product in mind.

2. Qualifications of the proposed principal/key investigator(s), supporting staff, and consultants; given the proposed product.

3. The potential of the proposed products for technological innovation.

4. The potential of the proposed products for commercial application.

5. The appropriateness of the budget requested, given the proposed products.

6. Adequacy and suitability of the facilities and research environment.

Procedures which will be used to evaluate applications submitted in response to our biomedical and health services research programs are as follows:

Applications will be initially screened to determine responsiveness. Those found to be non-responsive will be returned to the applicant. Those passing the initial screening will be reviewed for technical and scientific merit to determine the most promising approaches.

Review Process

Grant applications are subjected to a peer review process involving two sequential steps. For NIH, both of these steps are required by law. The first step is performed by the initial review groups (IRGs) composed primarily of non-federal scientists selected for their competence in particular scientific fields. The task of the IRGs is to evaluate applications for scientific and technical merit. For those applications recommended for approval, the reviewers provide a rating, suggest a funding level and duration of support and, on occasion, make highly specific recommendations related to the scope, direction and/or conduct of the proposed research. The second level of review is made by the national advisory council or board of the awarding component to which the grant application is assigned. These groups, composed of scientists, physicians, and leaders in public affairs, are chosen for their expertise, interest or activity in matters related to the awarding component's mission. Council or board recommendations are based on judgments about not only the technical merit of the proposed research but also its relevance to the mission of the awarding component. Generally, PHS may award a grant only if the corresponding application has been recommended for approval by a national advisory council or board. However, applications recommended for approval are not automatically funded.

Technical Evaluation Criteria

In considering the technical merit of each application, the following factors will be assessed:

1. The soundness and technical merit of the proposed approach and -

a. its expected results;

b. its envisioned incremental progress toward stated objectives; and

c. its relationship to the research topic.

2. Qualifications of the proposed principal/key investigator(s), supporting staff and consultants.

3. The potential of the proposed research for technological innovation.

4. The potential of the proposed research for commercial application.

5. The appropriateness of the budget requested.

6. Adequacy and suitability of the facilities and research environment.

EVALUATION OF BLOCK GRANTS

Question: During last year's hearing you indicated that it was too early to assess the gains in management efficiency by the block grants. Can you speak to that now?

Answer: As with any Federal spending, the Department has the program responsibility to ensure that the information needed for program management, oversight, and for policy and program decisions by the Congress and the Administration, is available. However, the kind of detailed evaluation appropriate for federally directed programs is not appropriate in the block grant program. Instead, we are focusing our information collection on ensuring that states have in place the mechanisms to comply with the block grant statutory requirements, such as public participation in planning the utilization of the block funds. We are also collecting information to help examine selected policy questions, such as the effect of the earmarks in several of the blocks, or the extent to which the States are able to take advantage of their discretion to set their own priorities.

Much pertinent information can be obtained from State plans and reports, and from cooperative and voluntary efforts by organizations such as the National Governors' Association. Therefore, we have concentrated our information collection efforts to date on these information sources.

DEPARTMENTAL REGULATIONS

Question: You state in your budget justification that "The Department will continue the effort...to simplify and consolidate regulations and to eliminate unnecessary regulations -- and also to strengthen those susceptible to fraud, waste and abuse.

A Lordly task — Give us some examples.

Answer: Former Secretary Schweiker established general task forces on regulatory relief which have produced the following tangible results:

1. FDA New Drug Applications

— published a draft regulation on new drug applications on 10/19/82. Final regulation is expected in June.

-- expect to publish draft regulation on investigatory new drug applications in May.

2. Regulations Affecting Grants to State Governments

— HHS submitted to OMB draft regulations on grants to State governments on 2/4/83. These regulations would add a new Part 98 which would simplify and reduce requirements on States and localities:

-- relies on States grants administration procedures and process, rather than imposing a Federal procedure on them;

-- substantially reduces accounting systems requirements; and

-- simplifies and reduces reporting requirements.

OMB is now reviewing these regulations with a view to making regulations of the Department of Education consistent with them.

3. State Plan and Management Information Systems

— developed draft guidance document for States to use in developing integrated eligibility determination and record-keeping systems in the AFDC, Medicaid and Food Stamps programs. This would:

— reduce States' record-keeping burdens; and

-- simplify application and eligibility determination in the States.

The draft guidance was developed after consultation with the Agriculture Department (for Food Stamps) and is now under review by the Secretary.

4. Hospital Regulations

— published draft regulation on hospital conditions of participation (i.e. health issues) on 1/4/83. Final regulation expected in late summer.

-- published final regulation (with comment period) on Imposition of Cost-Sharing Charges in Medicaid--(Co-payment) on 2/7/83.

-- expect to publish draft regulation on Deduction of incurred medical expenses ("Special down") in June, 1983 (i.e. simplified method for States to determine how to count medical expenses in determining eligibility for Medicaid — deals with bills incurred but not yet paid). This regulation is under review by the Secretary now.

DEPARTMENTAL REGULATIONS

Question: Where are you in the development in the regulation for the hospice program required by the Tax Equity Act of 1982?

Answer: A draft regulation has been prepared. We expect to issue a Notice of Proposed Rulemaking in the Federal Register shortly to elicit public comment before publishing a final regulation.

Question: Especially in an Administration which appears to be trying to eliminate duplication and excessive paperwork, it appears that an overlap in activities may be occurring among the offices of the Secretary/Under Secretary, the Assistant Secretary for Legislation and the Assistant Secretary for Planning and Evaluation. For example, "drafting, reviewing and implementing regulations" is listed as a function of each of these offices.

Do clear jurisdictional lines exist between each of these offices?

Answer: Yes, clear jurisdictional lines exist among these three offices. Each has a distinct functional area of responsibility. The Office of the Secretary/Under Secretary is responsible for the general management and direction of the Department. The Office of the Assistant Secretary for Legislation is responsible for presenting the Department's legislative program to the Congress and coordinating the Department's regulations with the Congress. The Office of the Assistant Secretary for Planning and Evaluation is responsible for developing the Department's planning and evaluation policies and procedure, including the formation of legislation and the oversight of research and regulatory analysis. Each office participates in the development of regulations primarily through the review of the final product prior to the Secretary's approval. The operating divisions, with assistance from the Office of the General Counsel, draft the vast majority of regulations. Each office reviews the regulations from its

functional perspective. The Legislation office, for example, would make certain that the regulation fulfills the intent of the Congress and that the Congress is kept informed about the progress the Department is making on the regulation. If an office during the review process, identifies a deficiency in its area of expertise, it will develop more appropriate language. In this sense, all offices participate in "drafting" regulations. Similarly, through their individual roles in developing regulations and overseeing the operating divisions, these offices do participate in aspects of "implementing regulations," although the operating divisions do the vast majority of the implementation work.

Although the Department has several offices involved with the development of regulations, each performs a unique service for that process.

Question: Do such activities as these frequently overlap?

Answer: No, I do not believe that the Department's conduct of activities, such as the development of regulations, overlap. They may appear to overlap because more than one office may be involved in different dimensions of the same activity. Having several offices participate is necessary because each brings a different but essential discipline to the process.

Question: A GAO report issued in July of 1982 showed that the chauffeur for the Office of the Secretary earned $35,060 in 1981. What was the chauffeur's salary in 1982, 1983, and what will it be in 1984?

Answer: The Secretary no longer has a chauffeur on her staff. During 1982, the position of chauffeur was discontinued, and the driver was reassigned to the Transportation Section in the Office of Management Services. Since that change was made, there are no chauffeurs in the Office of the Secretary or elsewhere in the Department.

During 1982, the individual who filled the position of chauffeur earned $29,380, including overtime pay. Because the position of chauffeur was discontinued, the 1983 and 1984 budgets do not include any funds for a chauffeur.

The chauffeur position was eliminated in order to provide safe, adequate transportation service to the Secretary in the most economical way. Because the Secretary of the Department of Health and Human Services has an extremely demanding work schedule, including early morning, late evening and weekend work, reasonable management practices dictated the use of more than one individual to fulfill her driving requirements.

Question: How do you justify this level of salary?

Answer: As noted earlier, we took specific steps to reduce the cost of providing driver service to the Secretary. We believe that assigning drivers from the Transportation Section meets the Secretary's extraordinary work demands while providing maximum safety economically.

Question: Who is authorized to use this chauffeur service?

Answer: The Secretary is the only individual assigned designated drivers from the Transportation Section. The remaining drivers in the Transportation Section provide services to the Secretary and, on a reservation basis, to the Under Secretary, Assistant Secretaries, Deputy Assistant Secretaries. or equivalent, on official HHS business. Other officials must compete for transportation services within the pool of drivers and vehicles.

ADVISORY COMMITTEES

Question: How many Advisory Committees are currently being funded by the Department? Please provide the name and annual cost of each committee.

Answer: As of December 31, 1982, there were 217 Advisory Committees being funded by the Department at a total estimated annual cost of $31,187,334. The name and annual cost of each committee is as follows:

Advisory Committees	Annual Cost
Advisory Board on Child Abuse and Neglect	$11,143
Advisory Committee to the Director, National Institutes of Health	95,322
Advisory Committe on Special Studies Relating to the Possible Long-Term Health	9,264
Aging Review Committee	338,772
Alcohol Biomedical Research Review Committe	98,000
Alcohol Psychosocial Reasearch Review Committee	94,000
Allergy and Immunology Study Section	116,631
Allergy, Immunology and Transplantation Committee	185,347
Anesthetic and Life Support Drugs Advisory Committee.	21,089
Animal Resources Review Committee	147,247
Anti-Infective Drugs Advisory Committee	23,541
Arteriosclerosis, Hypertension and Lipid Metabolism Advisory Committee	48,029
Arthritis Advisory Committee	39,562
Arthritis, Metabolism and Digestive Diseases Special Projects Review Committee	253,475
Bacteriology and Mycology Study Section	246,675
Basic Behavioral Processes Research Review Committee.	102,855
[illegible]ic Psychopharmacology and Neuropsychology [illegible]h Review Committee	213,943
[illegible]al Medicine Study Section	110,483
Behavioral and Neurosciences Study Section	297,554
Biochemical Endocrinology Study Section	135,332
Biochemistry Study Section	241,859
Biomedical Library Review Committee	94,555

Biomedical Sciences Study Section	233,193
Biometry and Epidemiology Contract Review Committee	94,557
Bio-Organic and Natural Products Chemistry Study Section	119,843
Biophysical Chemistry Study Section (formerly Biophysics and Biophysical Chemistry B Study Section)	135,694
Biopsychology Study Section	137,837
Biotechnology Resources Review Committee	28,099
Bladder and Prostatic Cancer Review Committee	126,536
Blood Diseases and Resources Advisory Committee	92,942
Blood Products Advisory Committee	59,524
Board of Regents of the National Library of Medicine	51,996
Board of Scientific Couselors, Division of Cancer Biology and Diagnosis	36,888
Board of Scientific Counselors, Division of Cancer Cause and Prevention	75,110
Board of Scientific Counselors, Division of Cancer Treatment	159,538
Board of Scientific Counselors, Division of Resources Centers and Community Activities	114,342
Board of Scientific Counselors National Eye Institute	14,568
Board of Scientific Couselors, National Heart, Lung and Blood Institute	14,007
Board of Scientific Counselors, National Institute on Aging	12,182
Board of Scientific Counselors, National Institute of Allergy and Infectious Diseases	41,259
Board of Scientific Counselors, National Institute Of Arthritis, Diabetes and Digestive and Kidney Diseases (Formerly Arthritis, Metabolism and Digestive Diseases)	17,796
Board of Scientific Counselors, National Institute of Child Health and Human Development	10,764
Board of Scientific Couselors National Institute of of Dental Research	11,843
Board of Scientific Counselors, National Institute on Drug Abuse	0
Board of Scientific Counselors National Institute of Environmental Health Sciences	36,277
Board of Scientific Counselors National Institute Of Mental Health	36,402
Board of Scientific Counselors, National Institute Of Neurological and Communicative Disorders and Stroke	18,501
Board of Scientific Counselors, National Library of Medicine	11,500
Board of Tea Experts	5,000
Breast Cancer Task Force Committee	53,765
Cancer Center Support Review Committee	270,134
Cancer Clinical Investigation Review Committee	129,066
Cancer Control Grant Review Committee	143,941
Cancer Control Intervention Programs Review Committee	45,362
Cancer Preclinical Program Project Review Committee	391,178
Cancer Research Manpower Review Committee	134,269

Cancer Resources and Repositories Contracts Review Committee	67,653
Cancer Regional Studies Review Committee	58,649
Cardiology Advisory Committee	51,285
Cardiovascular and Pulmonary Study Section	168,065
Cardiovascular and Renal Drugs Advisory Committee	43,963
Cardiovascular and Renal Study Section	131,824
Cell Biology Study Section	155,244
Cellular and Molecular Basis of Disease Review Committee	115,219
Chemical Pathology Study Section	132,457
Circulatory System Devices Panel	23,984
Clinical Applications and Prevention Advisory Committee	24,558
Clinical Cancer Education Committee	109,249
Clinical Cancer Program Project Review Committee	467,455
Clinical Chemistry and Hematology Device Panel	107,869
Clinical Sciences Study Section	209,533
Clinical Trials Committee	92,314
Clinical Trials Review Committee	76,210
Cognition, Emotion and Personality Research Review Committee	113,386
Communicative Disorders Review Committee	151,697
Criminal and Violent Behavior Review Committee	126,514
Dermatologic Drugs Advisory Committee	24,415
Developmental Therapeutics Contracts Review Committee	116,857
Device Good Manufacturing Practice Advisory Committee	8,268
Diagnostic Radiology Study Section	133,289
Drug Abuse Advisory Committee	40,784
Drug Abuse Biomedical Research Review Committee	262,411
Drug Abuse Clinical, Behavioral and Physchosocial Research Review Committee	390,570
Endocrinologic and Metabolic Drugs Advisory Committee	42,254
Endocrinology Study Section	154,183
Environmental Health Sciences Review Committee	312,513
Epidemologic and Services Research Review Committee	269,901
Epidemiology and Desease Control Study Section	268,575
Epilepsy Advisory Committee	25,461
Experimental Cardiovascular Sciences Study Section	111,624
Experimental Immunology Study Section	116,000
Experimental Therapeutics Study Section	136,814
Experimental Virology Study Section	119,759
Federal Council on the Aging	175,000
Fertility and Maternal Health Drugs Advisory Committee	49,333
Frederick Cancer Research Facility Advisory Committee	40,813
Gastrointestinal Drugs Advisory Committee	40,626
General Clinical Research Centers Committee	249,389
General Medical Devices Panel	56,459
General Medicine A Study Section	191,820
General Medicine B Study Section	120,261
General Research Support Review Committee	248,495
Genetic Basis of Disease Review Committee	105,508
Genetics Study Section	151,095
Health Care Technology Study Section	153,289
Health Services Research and Developmental Grants Review Committee	257,609

Heart, Lung and Blood Research Review Committee A....	562,699
Heart, Lung and Blood Research Review Committee B....	538,517
Hematology Study Section.....	240,621
Human Development and Aging Study Section (formerly Humand Development Study Section).....	249,240
Human Embryology and Development Study Section.....	131,994
Immunization Practices Advisory Committee.....	61,950
Immunobiology Study Section.....	128,756
Immunobiology Sciences Study Section.....	121,664
Immunology and Microbiology Devices Panel.....	95,808
Interagency Committee on Federal Activities for Alcohol Abuse and Alcoholism.....	34,000
Large Bowel and Pancreatic Cancer Review Committee...	146,967
Mammalian Genetics Study Section.....	126,805
Maternal and Child Health Research Committee.....	234,960
Medical Radiation Advisory Committee.....	22,162
Medicinal Chemistry Study Section (formerly Medicinal Chemistry A Study Section).....	134,300
Mental Health Research Education Review Committee....	372,553
Mental Health Small Grant Review Committee.....	230,714
Mental Health Behavioral Sciences Reasearch Review Committee.....	30,895
Mental Retardation Research Committee.....	180,650
Metabolism Study Section.....	147,351
Metallobiochemistry Study Section.....	110,115
Microbial Physiology and Genetics Study Section.....	217,126
Microbiology and Infectious Deseases Advisory Committee.....	143,518
Mine Health Research Advisory Committee.....	94,787
Minority Access to Research Careers (MARC) Review Committee.....	198,199
Molecular Biology Study Section.....	136,386
Molecular and Cellular Biophysics Study Section.....	122,988
Molecular Cytology Study Section.....	125,909
National Advisory Allergy and Infectious Diseases Council.....	245,187
National Advisory Child Health and Human Development Council.....	267,144
National Advisory Council on Aging.....	168,068
National Advisory Council on Alcohol Abuse and Alcoholism.....	36,540
National Advisory Council on Drug Abuse.....	57,641
National Advisory on Health Professions Education....	106,000
National Advisory Council on Migrant Health.....	12,100
National Advisory Council on the National Health Service Corps.....	28,677
National Advisory Council on Nurse Training.....	68,132
National Advisory Dental Research Council.....	83,593
National Advisory Environmental Health Sciences Council.....	67,666
National Advisory Eye Council.....	94,642
National Advisory General Medical Sciences Council...	306,822
National Advisory Mental Health Council.....	83,790
National Advisory Neurological and Communicative Disorders and Stroke Council.....	221,961
National Advisory Research Resources Council.....	134,773
National Arthritis Advisory Board.....	300,000

National Arthritis, Diabetes and Digestive and Kidney Deseases Advisory Council	354,216
National Cancer Advisory Board	692,827
National Commission on Social Security Reform	1,036,539
National Committee on Vital and Health Statistics	40,163
National Council on Health Planning and Development	74,196
National Diabetes Advisory Board	300,000
National Digestive Diseases Advisory Board	300,000
National Heart, Lung and Blood Advisory Council	517,650
National Institute of Dental Research Programs Advisory Committee	20,091
National Institute of Dental Research Special Grants Review Committee	139,061
National Toxicolgy Program Board on Scientific Counselors	86,061
Neurological Disorders Program-Project Review A Committee	283,301
Neurological Disorders Program-Project Review B Committee	254,758
Neurological Sciences Study Section	134,687
Neurology A Study Section	123,249
Neurology B Study Section	276,935
Nutrition Study Section	141,181
Oncologic Drugs Advisory Committee	30,167
Ophthalmic, Ear, Nose, Throat and Dental Devices Panel	118,091
Oral Biology and Medicine Study Section	227,409
Orthopedics and Musculoskeletal Study Section	103,755
Pathobio-Chemistry Study Section	127,772
Pathology A Study Section	129,774
Pathology B Study Section	113,994
Peripheral and Central Nervous System Drugs Advisory Committee	32,421
Pharmacological Sciences Review Committee	148,970
Pharmacology Study Section	132,085
Physical Biochemistry Study Section	119,528
Physiological Chemistry Study Section	130,617
Physiology Study Section	135,306
Population Research Committee	197,056
President's Cancer Panel	45,106
President's Committee on Mental Retardation	687,303
President's Council on Physical Fitness and Sports	677,039
Psychopharmacologic Drugs Advisory Committee	54,900
Psychopathology and Clinical Biology Research Review Committee	255,674
Pulmonary-Allergy Drugs Advisory Committee	37,079
Pulmonary Diseases Advisory Committee	70,296
Radiation Study Section	138,812
Radiological Devices Panel	14,031
Radiopharmaceutical Drugs Advisory Committee	28,232
Rape Prevention and Control Advisory Committee	51,925
Recombinant DNA (Deoxyribonucleic) Advisory Committee	129,173
Reproductivity Biology Study Section	185,177
Research Manpower Review Committee	91,900
Research Scientist Development Review Committee	118,784
Respiratory and Nervous System Devices Panel	52,335
Safety and Occupational Health Study Section	210,763

Sensory Disorders and Language Study Section	156,964
Science Advisory Board to the National Center for Toxicology Research	10,054
Scientific Programs Advisory Committee, NINCDS (formerly Neurological and Communicative Disorders and Stroke Science Information Program Advisory Committee)	36,111
Sickle Cell Disease Advisory Committee	37,603
Social Sciences and Population Study Section	142,403
Surgery, Anesthesiology and Trauma Study Section	118,442
Surgery and Bioengineering Study Section	111,090
Surgical and Rehabilitation Devices Panel	63,290
Technical Electronic Product Radiation Safety Standards Committee	34,410
Toxicology Study Section	182,094
Treatment Development and Assessment Research Review	282,206
Tropical Medicine and Parasitology Study Section	129,735
Vaccines and Related Biological Products Advisory Committee	50,311
Virology Study Section	128,333
Vision Research Program Committee	130,563
Visual Sciences A Study Section	243,096
Visual Sciences B Study Section	128,813
1982 Advisory Council on Social Security	17,963
Total	31,187,334

ACTIVITIES OF THE INSPECTOR GENERAL

Question: You have been Inspector General since June 1, 1981, the date the Senate confirmed your appointment. You began a series of internal management changes to "maximize the effectiveness of available resources" which were part of a "shift in priorities and scope of" your office and according to your Budget Justificiation "are in the final stages." What are the new priorities? What has your office accomplished with them?

Answer: Since assuming the position of Inspector General, I ...ent a considerable amount of my time and attention developing ...ucture to efficiently and effectively address fraud, abuse and mismanagement problems within the Department and simultaneously accelerate our efforts to pursue abusers of the Departmental programs. The following examples exemplify the direction of the OIG.

- Major changes have been effected in the types of activities performed by the Office of Audit. Rather than devoting substantial resources for the audit of expenditures of federal dollars, by colleges and universities we have determined that these OMB requirements can best be met by contracting with State and local audit sources. This strategy allows OIG resources to concentrate on SSA, Medicare and Medicaid which are high priorities of the Executive and Legislative Branches of the Government.

- Formerly significant activities focused on external entities such as the close-out of contracts and grants. I have elected to reverse this trend to one of placing the major emphasis on the internal departmental activities of SSA, Medicaid, and Medicare which account for the major portion of Department expenditures. Adherence to these new work plan objectives is essential if we are to substantially decrease the means which permit fraud, abuse and mismanagement.

This redirection of audit, investigative and integrity resources to an active focus on the large dollar, managerially complex programs such as Social Security and Medicaid/Medicare appears to be the correct approach and bodes well for significantly greater productivity in FY 83 and FY 84.

The following charts provide the data for the first 6 months of FY 1983 which exceed accomplishments in previous 6 month periods and represent the effectiveness of this redirection.

H H S

O I G R E D I R E C T I O N

In the past, a considerable amount of audit resources were spent determining the allowability of grant and contract costs claimed by : Colleges/Universities and State and Local Governments. In addition, substantial time was spent reviewing contract closing statements. When compared to total Departmental expenditures, a disproportionate amount of time was being spent on these grantees/contractors instead of our largest and most expensive responsibilities--Health and Social Security.

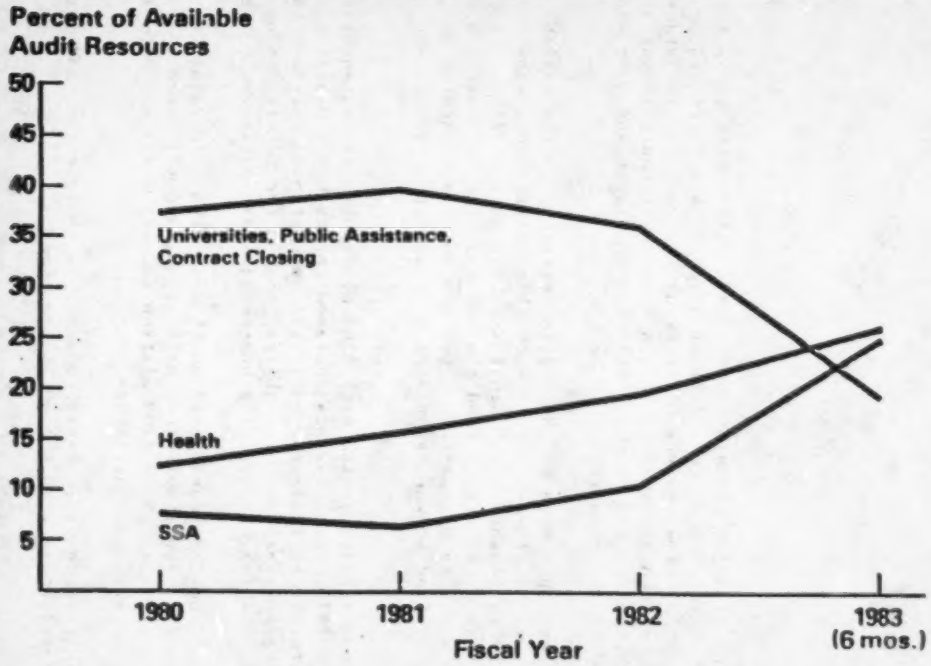
In 1982, auditors began digging deep into much of the virgin territory in the Health Financing and Social Security programs. In consonance with this redirection, many audits took on a new form. Past audits were financial in nature with emphasis on allowability of charges. The thrust of our new audits is to go beyond the trans-action and search out problem areas from a larger more systemic perspective. Our new role is to act as an "agent-for-change" to correct identified weaknesses giving rise to fraud, waste, and abuse.

This new audit thrust began to show steady results with $501 million in estimated savings from September 1982 through March 1983. These savings represent areas where Department managers have made formal committments to implement audit recommendations. Actions taken or planned should: (1) prevent improper expenditures/obligations in the future and/or (2) improve agency systems and operations thereby avoiding unnecessary expenditures.

Cost savings differ substantially from cost questioned which deal with (1) violation of regulation or law, (2) deviations from acceptable cost principles, and (3) funds already spent. On the average, auditors questioned about $100 million (covers a six month period) in costs claimed by Department grantees and contractors.

We are most pleased with the results to date in carrying out this redirection, and hope to report on further meaningful accomplishments in the months to come.

OIG AUDIT REDIRECTION



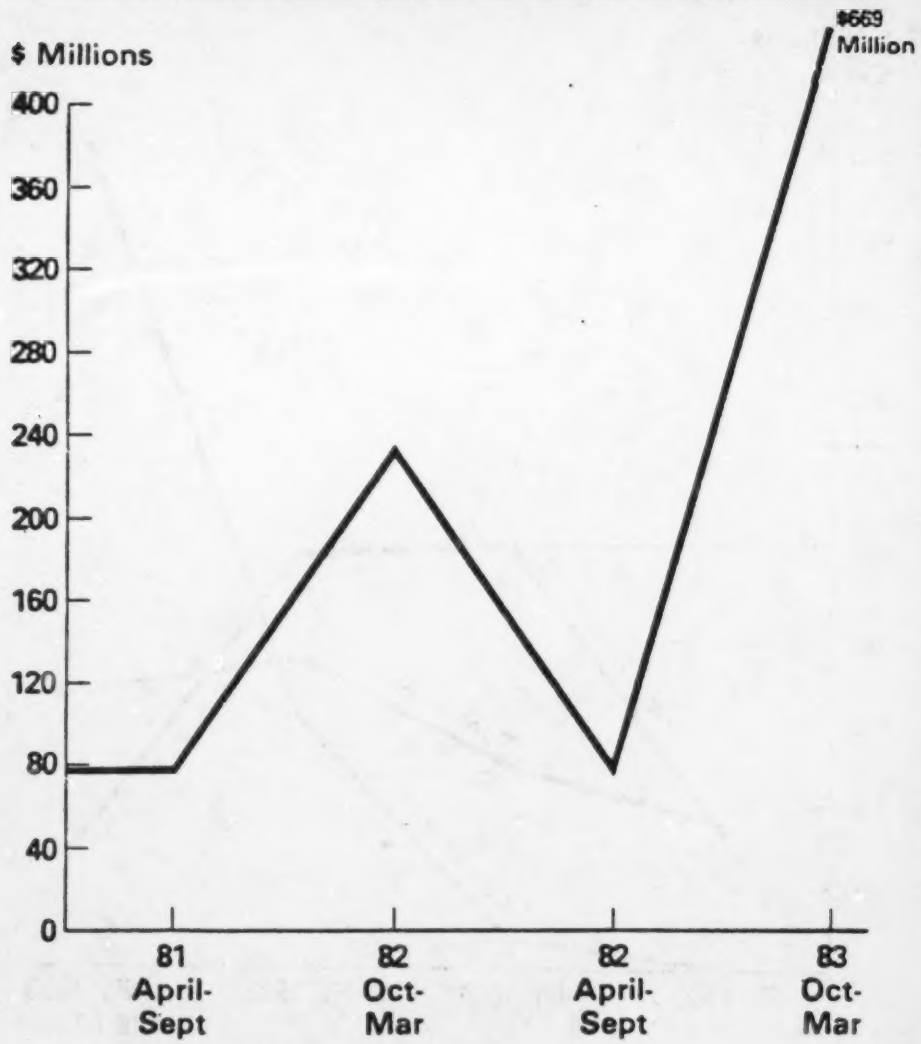
OFFICE OF INSPECTOR GENERAL

STATISTICS - FY 1980 - 1983

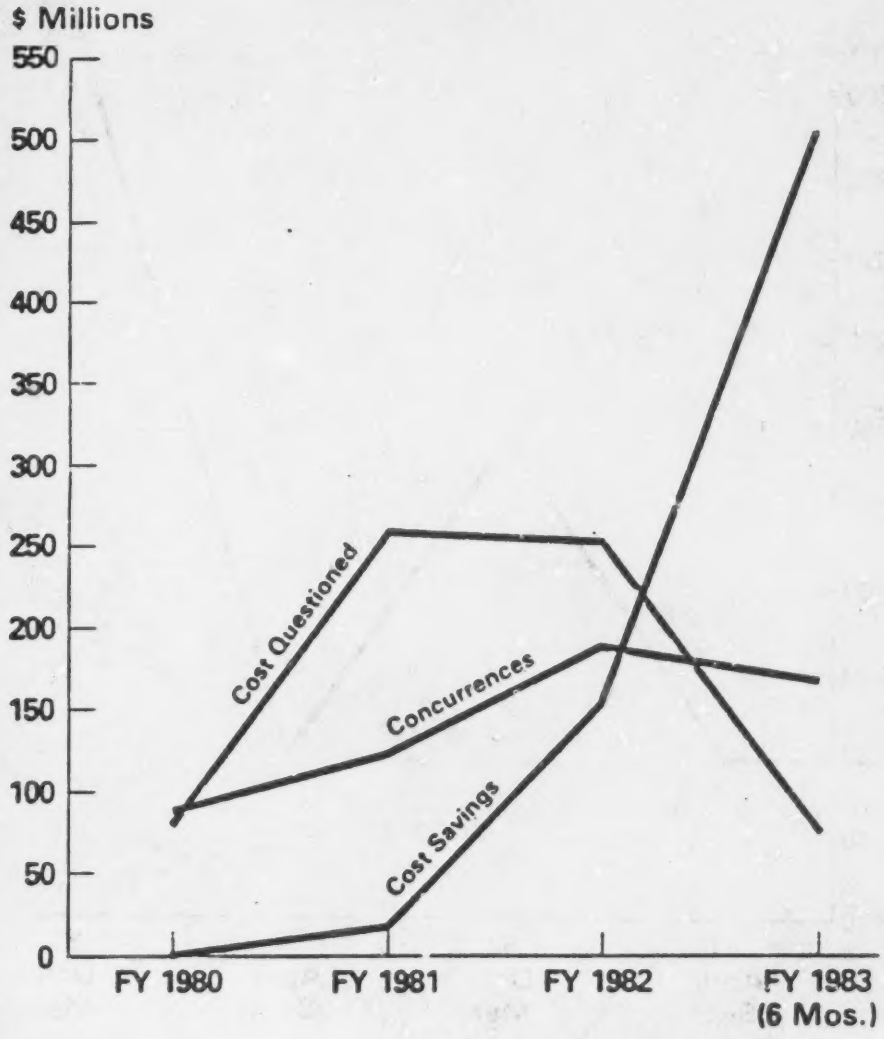
(in $Millions)

FISCAL YEAR:	1980	1981	1982	1983 (6 Mos.)
Cost Savings	- 0 -	16.0	153.0	501.5
Questioned Costs	78.3	256.0	250.8	75.8
Concurrences	86.6	122.5	187.3	166.7

COST SAVINGS/AUDIT CONCURRENCES
APRIL - MARCH 1983



OFFICE OF INSPECTOR GENERAL STATISTICS



OIG RECOMMENDATIONS COULD SAVE HEALTH PROGRAMS $461

o $157 million could be saved by requiring mandatory second surgical opinions for selected surgeries

o $64 million could be saved if hospitals could obtain a more favorable price for pacemakers.

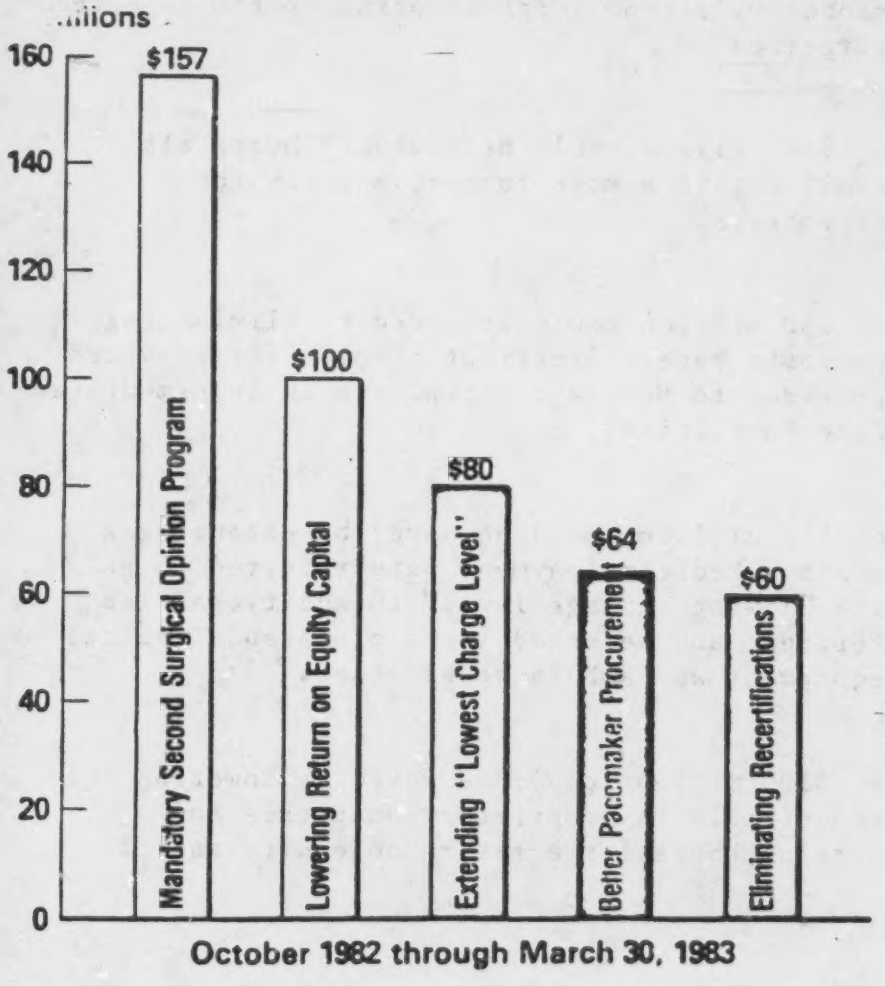
o $60 million could be saved by eliminating periodic recertifications of need for services provided to Medicaid recipients in Intermediate Care Facilities.

o $80 million could be saved by extending a maximum Medicare payment rate referred to as the "lowest charge level" to additional lab serices and selected items of durable medical equipment and ambulance services.

o $100 million could be saved by lowering the amount paid to proprietary hospitals and nursing homes for a return on equity capital.

—$461 MILLION—

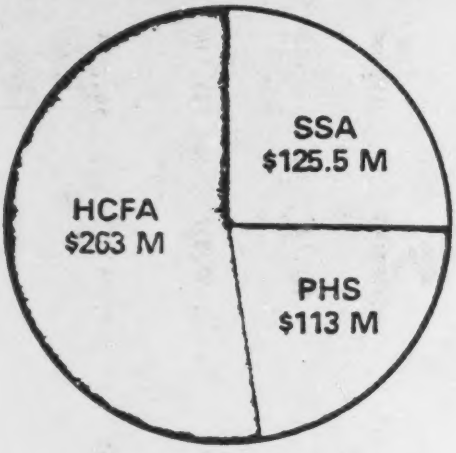
COST SAVINGS IF INSPECTOR GENERAL HEALTH RECOMMENDATIONS ARE IMPLEMENTED



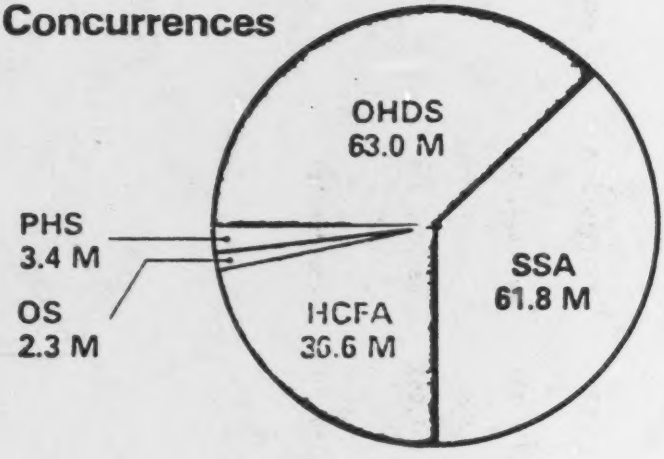
October 1982 through March 30, 1983

COST SAVINGS AND CONCURRENCES BY OPERATING DIVISION OCTOBER 1, 1982 - MARCH 31, 1983

Savings



Concurrences



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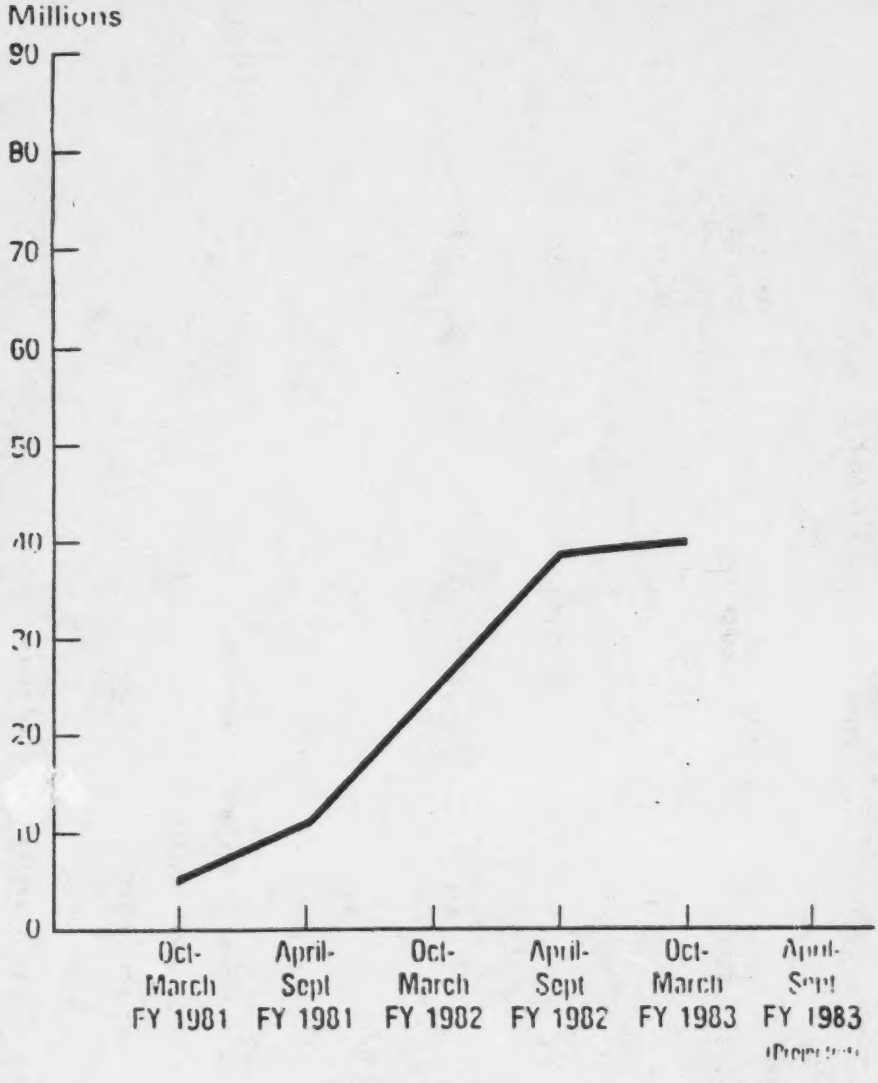
INVESTIGATIVE RECOVERIES

	FINES	RESTITUTIONS	SETTLEMENTS	RECOVERIES	SAVINGS	TOTAL
FY 1981	$1,780,250	$2,674,450	-0-	$ 2,302,121	$ 3,555,078	$10,311,899
FY 1982	$ 657,065	$1,017,256	$ 70,783	$ 8,943,857	$27,733,734	$38,422,695
FY 1983 (6 MONTH)	$ 360,207	$1,204,513	$1,277,930	$31,296,933	$ 5,561,723	$39,701,306

INVESTIGATIVE RECOVERIES



INVESTIGATIVE CASE RESULT

	APRIL 1981 - SEPT. 1981	OCT. 1981 - MARCH 1982	APRIL 1982 - SEPT. 1982	OCT. 1982 - MARCH 1983*
PRESENTATIONS	141	160	132	197
DECLINATIONS	94	69	35	42
DECLINATION RATE	67%	43%	27%	21%
CONVICTIONS	85	106	95	164

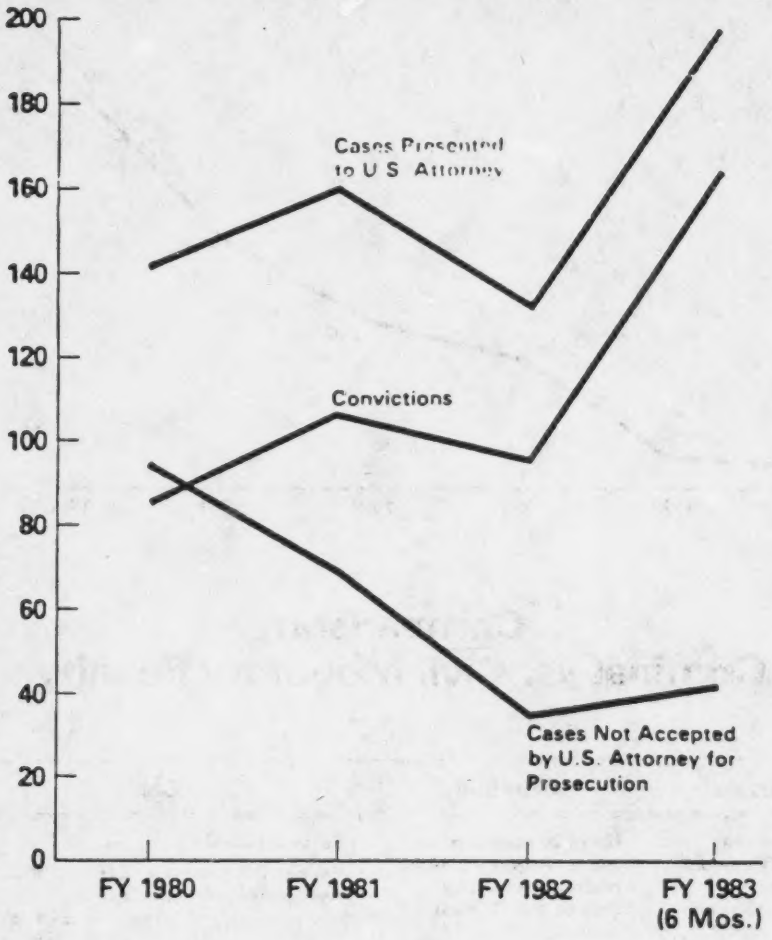
PRESENTATIONS: CASES SUBMITTED TO THE U.S. ATTORNEY

DECLINATIONS : U.S. ATTORNEY DENIALS

CONVICTIONS : COURT ACTION TAKEN

*Does Not Include Program Integrity Accomplishments

INVESTIGATIVE RESULTS



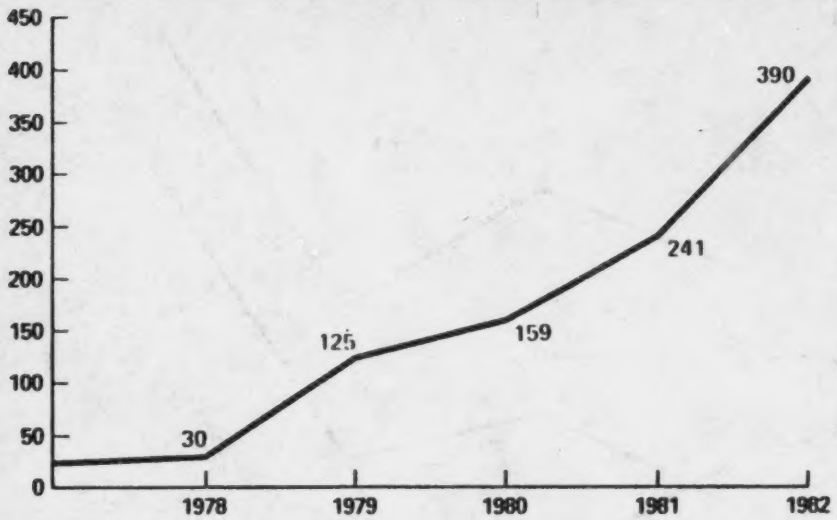
SMFCU SAVINGS

Calendar year:	
1978	$4,777,288
1979	13,109,607
1980	20,032,651
1981	34,646,581
1982	35,648,581
Total	108,214,708

Figures represent overpayments, fines, restitutions.

HEALTH CARE PROVIDER CONVICTIONS

STATE MEDICAID FRAUD CONTROL UNIT



Comparison
Criminal vs. Civil Monetary Penalty

Example	Criminal	Civil
Doctor submits 300 false Medicaid or Medicare claims @ $50 each, totaling $15,000.	Up to 20 counts maximum. A guilty plea normally would be only to 2 or 3 "Best" counts. Penalty is usually a suspended sentence; a fine of maybe $5,000 and some sort of restitution.	Potential Liability: Penalty 300 counts x $2,000 = $600,000 Assessment — Twice the Claims = $ 30,000 Total Potential Liability = $630,000

Question: In another area you are responsible to assure that departmental regulations include provisions to prevent waste, fraud and abuse. What have you accomplished in this area? Do you have a current estimate of the amount of losses to the Department due to fraud, waste and abuse?

Answer: Over the past two years, we have significantly strengthened our capacity for reviewing Departmental regulations to insure that proposed new rules contain appropriate safeguards against waste, fraud and abuse. We have established a special division within OIG that coordinates our regulation review activity. The division reviews over 200 regulations annually that are submitted to OIG for comment by the Secretary. We have made several significant recommendations to the Secretary designed to strengthen program management and policy. Examples are:

1. OIG provided the only cost data available on End Stage Renal Dialysis services to the Secretary as the Department formulated appropriate rates for ESRD services.

2. The OIG recommended, and the Secretary adopted, tighter standards for the voluntary certification of medical insurance companies under the "Medi-gap" program.

3. The OIG has provided the Secretary suggestions concerning standards for providing utilization review in the Medicare program.

4. The OIG recommended, and the Secretary adopted, regulation changes for the Hill Burton Uncompensated Care program that would insure better access of the poor to health services while, at the same time, not imposing additional administrative burden on hospitals.

Currently, the OIG is developing procedures to become involved in regulation decisions early in the Department's drafting process. We are, for example, examining carefully the prospective payment experience of New Jersey, as well as the rate setting activities of other states. We want to provide information to the Secretary and the Health Care Financing Administration on procedural safeguards that should be built into the new medicare prospective payment system for hospitals.

We do not have a current estimate of the amount of losses to the Department due to fraud, waste, and abuse.

Question: How do you follow-up on recommendations made to the Department?

Answer: When the OIG nonconcurs or has additional recommendations on a Departmental regulation, we work with program officials to resolve the issue and, where appropriate, change the regulation to include our recommendations. If the program officials and the IG cannot come up with a solution, they are surfaced to the Secretary for resolution.

STATE MEDICAID FRAUD UNITS

Question: In March of 1982 the House Select Committee on Aging reported that despite the prevalence of Medicaid fraud, State enforcement efforts were ineffective in many areas. At that time 20 States had not established Fraud Control Units despite the availability of Federal matching funds at a level of 90%. What recent actions have the States taken to increase the number of anti-fraud units?

Answer: Although published in March 1982, the report of the House Select Committee on Aging based its conclusions upon data through December 31, 1980. Since that time, the States of Indiana and Virginia have established Medicaid Fraud Control Units. In addition, the Office of the Inspector General has embarked upon a pro-active project to contact those States which do not presently have a Medicaid Fraud Control Unit for the purposes of acquainting them with the administration of the program, and the advantages of participating. Thus far, Minnesota, Iowa, Oklahoma, New Mexico, Missouri and South Dakota have all expressed interest in applying.

Question: Is there evidence that States are curtailing their Medicaid anti-fraud and abuse activities in response to fiscal pressures?

Answer: No, there is no evidence that States are curtailing their Medicaid anti-fraud and abuse activities in response to fiscal pressures.

Question: Has there been any change in the effectiveness of the State Medicaid Fraud Control Units?

Answer: As Medicaid Fraud Control Units gain expertise in this difficult area of fraud, their ability to investigate and prosecute fraud within the Medicaid program increases. Since the inception of the program, each year has experienced a substantial increase in the number of convictions obtained by the SMFCUs. In addition, there has been a corresponding increase in the ability of fraud units to return to the government (through fines, restitutions and overpayment identified) millions of dollars.

Question: What is the rate of return on funds expended for this purpose?

Answer: Since the inception of the program to September 20, 1982, over $100 million dollars has been returned through fines and restitution or identified as overpayments. While the amount of actual dollars recovered or saved may be a good measure of the success of a SMFCU, the deterrent effect, that is, how much fraud or program abuse is prevented (by publicity, convictions) may be an even more significant, albeit unmeasurable, factor.

Through FY 1982, the Inspector General's Office has provided approximately $100 million to support the SMFCU units. Therefore, the data indicates a dollar for dollar return.

STATE MEDICAID FRAUD CONTROL LIMITS — TECHNICAL DECREASE

Question: You show a built-in decrease of $10 million for the State Medicaid Fraud Control Units. Could you please explain what this decrease is?

Answer: The $10 million decrease included in the built-in decreases displayed on pages 80 and 81 of our justification occurs as a one-time adjustment in current year funding as the State Medicaid Fraud Control Unit account converts from a "borrowing" type authority to an "advance appropriation" type financing authority.

Starting with the FY 1983 budget request, advance appropriation authority replaced the borrowing authority in this program. Once the $10 million in advance appropriations (requested as part of the FY 1983 budget) for FY 1984 became enacted (P.L. 97-277) a technical reduction of $10 million in the FY 1984 request before you became necessary.

The important point in all this is that henceforth, the OIG SMFCU budget year request for budget authority and appropriations will be the same thereby ending the confusion experienced in prior years.

In addition, the $24.9 million FY 1984 budget request for SMFCU, combined with the 1985 advance appropriation of $9 million, will fully meet all participating States' needs.

SPECTRE PROGRAM

Question: What is project "Spectre" and what has it accomplished?

Answer: Project Spectre involves the computer matching of SSA beneficiary roles with Health Care Financing Administration (HCFA) decedent roles to detect, investigate and prosecute individuals suspected of fraudulently obtaining SSA Trust Fund monies being paid to deceased beneficiaries. To date, this project has resulted in: The removal of 5,263 names from the beneficiary roles, recovery of $7,605,218 for SSA, and a savings of over $25.2 million.

Question: Do you have any other plans in this area that you can expand upon?

Answer: Yes, the HHS/OIG is the pacesetter in the use of computer technology to combat fraud, waste and abuse having developed approximately two-thirds of all Federal computer matching programs. The OIG uses computer techniques in reviewing HHS programs and provides assistance to Federal and State agencies and contractors. Among significant fraud detection initiatives, using the computer as a tool, are:

- Using computer screens we detected fraudulent medicaid provider billing practices in two states. If our findings

here hold true for other states, potential recovery exceeds $7 million.

- Using computer matches we assisted state and county welfare investigators and prosecutors in finding AFDC cases where recipients are already receiving previously unreported SSA or SSI benefits. This project has also helped to report false cases where recipients have reported false Social Security numbers to AFDC officials in order to obtain benefits.

Question: Your 1984 Budget Justification indicates that "Program Integrity" functions were transferred from the Social Security Administration and the Health Care Financing Administration to your office. Do you perceive these functions differently than the Social Security Administration and the Health Care Financing Administration, and how do you propose to administer them?

Answer: The transfer of the program integrity and validation functions from SSA and HCFA concentrates into one office expertise for investigating instances of suspected fraud, abuse and waste in the Department's programs and activities. This consolidation will reduce any potential overlap between the OIG and Operating Divisions. These resources will be administered in the same fashion as our audit, investigation and inspection components.

Our perception of these functions directly correlate to the Congressional intent and statutory provisions which constitute our reason for existing. We perceive the OIG role as being an independent and objective arm of the Congress by providing sound policy and managerial direction in the development and implementation of Departmental programs. These transfers will also insure further identification and protection against fraud, abuse and mismanagement in the Social Security, Medicaid, and Medicare programs. In summary these transfers will improve productivity and cost-effectiveness in these major programs through the provision of an objective and independent perspective.

Question: What resources were transferred?

Answer: The FY 1983 and FY 1984 resources transferred are:

($ in thousands)
(comparable to FY 1984)

	FY 1983			FY 1984		
	SSA	HCFA	Total	SSA	HCFA	Total
Dollars	$7,442	$7,881	$15,323	$6,915	$8,000	$14,915
Positions	176	176	352	176	176	352
FTE	188	170	358	188	170	358

Question: Did any employees lose their job or get downgraded?

Answer: These transfers took place without one job loss or downgrade of position.

CIVIL MONEY PENALTY PROGRAM

Question: What exactly is the Civil Money Penalty Program?

Answer: The Civil Money Penalty Program was authorized by Section 2105 of the Omnibus Reconciliation Act of 1981. It permits the Department to impose penalties and assessments administratively for the filing of false or certain other improper claims in the Medicare, Medicaid, or Maternal and Child Health Services Block Grant Programs. The monetary penalties which we may assess under this program will serve as a deterrent by convincing a would-be defrauder that the risk of discovery and punishment for filing false claims far out weighs the potential reward.

The law provides that in addition to the penalty of not more than $2,000 per false claim, we may seek an additional assessment of not more than twice the amount claimed for each item or service, in lieu of damages sustained by the United States or a State Agency because of such claim.

The Secretary delegated the authority to propose penalties to the Inspector General in order to strengthen the Inspector General's ability to carry out his statutory responsibility to control fraud, abuse and waste in HHS programs. Individuals against whom fines are proposed are entitled to a hearing. The Inspector General's position at any such hearing would be represented by attorneys in the Office of General Counsel. Administrative law judges supported by the HHS Grants Appeals Board would be assigned to hear the cases.

Question: Are you requesting additional resources to administer this program?

Answer: No. With the transfer of the HCFA program integrity function and some staff resources to OIG we are able to handle this additional work load without increased staff.

Question: Do you have any other plans in this area that you can expand upon?

Answer: Yes, on November 10, 1980 the Department issued a regulation entitled: "Debarment and Suspension from Eligibility for Financial Assistance". This regulation established guidelines and procedures for suspending and debarring individuals, institutions and business entities from participation in departmental discretionary grant programs upon showing that the person or institution was guilty of fraud or abuse in the conduct of their business with government. Similar regulations have been published for debarments in connection with contracts.

The suspension and debarment regulations were published in 45 FR 67262 (dated October 9, 1980). Under these regulations, the Secretary may suspend a person or organization from participation in departmental programs when (s)he "believes that grounds for debarment exist." Suspension is immediate, and lasts until full debarment proceedings are completed. If the problems are not sufficiently serious to warrant a suspension or debarment, the

Department could take less severe action, such as greater monitoring of the programs, special restrictions or etc. In order to fully inform appropriate officials of the status of program participants who have come to the attention of OIG, this office prepares an Advice of Scheduled Investigation (ASI) form when a case is opened, and provides a copy of the final investigative report to the program officials when an investigation is completed. The ASI advises the program officials that an investigation of a person or institution has been initiated, and what the allegations are against them. The investigative report provides information as to the evidence which supports or denies the allegations, and also any prosecutive action taken by the Department of Justice on the case.

COMPLAINT PROJECTIONS/INVESTIGATION PROCESS

Question: How do you project the expected number of complaints that you may receive in FY '84?

Answer: Complaint receipts were determined by looking at the average annual rate of change in the number of complaints received during the last five years. The average rate of increase (1.3 percent) was applied to the number of complaints received in fiscal year 1982 to derive projections for fiscal years 1983 and 1984.

Question: How many of these complaints will be investigated?

Answer: Approximately 40 percent of complaints are investigated. We anticipate that this proportion will continue in fiscal year 1984.

Question: How do you determine which complaints should be investigated? Please describe the entire investigation process in detail.

Answer: Complaints are investigated when our initial staff review determines that OCR has jurisdiction. This means that the subject of the complaint is a recipient of HHS funds and that the recipient is allegedly violating a law that is enforced by OCR. Complaints are not investigated if: OCR does not have jurisdiction; the complaint is not filed timely as defined by the regulations; the complaint is incomplete; the complainant cannot be located or declines to cooperate; the complainant withdraws the complaint; or, the case is referred to another agency which has subject matter and funding jurisdiction.

Most complaints are received in the regional offices. After all basic identifying information has been obtained and a determination is made that OCR has jurisdiction, the case is assigned to an Equal Opportunity Specialist for investigation. The recipient agency is notified that a complaint has been filed and is requested to submit information pertinent to making a compliance determination. If, an on-site visit is required, the investigator will set up a time for the visit with the recipient. Following data collection and on-site visits, investigators evaluate all the relevant facts and circumstances to determine the recipient's compliance status. At this point, a letter of findings will be issued to the

recipient setting forth the determination. If the finding is that the recipient is not in compliance, OCR will require development of a corrective action plan. We negotiate with the recipient, provide technical assistance, and make every effort to work out a voluntary settlement. If, however, a voluntary agreement can't be worked out, enforcement action is taken. In certain cases, when both the complainant and the alleged violator are willing to try to work out an agreement prior to an investigation, we will use an early complaint resolution process to try to reach a settlement. If early complaint resolution is rejected by either of the parties to a complaint, or, if it is unsucessful, an investigation will follow immediately.

AGE DISCRIMINATION COORDINATION FUNCTIONS

Question: The Age Discrimination Act of 1975 assigned coordination responsibilities to the old Department of Health, Education, and Welfare. These are now vested in the Department of Health and Human Services. Specifically, the Department is to ensure consistency in the implementation of regulations for approximately 30 agencies responsible for enforcing nondiscrimination on the basis of age in federally assisted programs. The Act set specific deadlines for agencies to publish and submit these regulations for Departmental approval. On the basis of these deadlines, most agencies' regulations are now nearly three years overdue. The Department has just published its own Age Discrimination Act regulation last December.

How long do you anticipate it will take the Department to get these agencies to follow suit?

Answer: As of April 15, 1983 only six agencies have not published proposed rules. Four agencies, including HHS, have published final rules and twelve agencies have submitted final rules to OCR for clearance. Another six agencies are developing final rules. We are continuing to follow up with all agencies to expedite the rule-making process. We cannot now predict when all final agency regulations will be issued. One of the complications in completing this process is that litigation has been initiated by several aging organizations in connection with the issuance of the HHS final rule in December. The resolution of that litigation may affect the substance of other agency rules. Thus, final action on those agency regulations may have to await resolution of the issues raised in the litigation.

Question: When can we expect OCR to establish a time frame for agencies to comply with the issuance of regulations?

Answer: The government-wide coordinating regulation established a time frame for issuing proposed and final regulations. Of the 28 agencies required to develop regulations, only six have yet to publish proposed rules. Although HHS has no authority to mandate particular agency action by a set date, we are working with all agencies to expedite the process.

Question: How many staff will OCR assign to this project for coordination functions with these agencies?

Answer: At the present time, the Division of Policy and Special Projects/OCR is responsible for carrying out the coordination functions. The Division is assisted by the Civil Rights Division of the Office of the General Counsel. Four staff members from the Division have carried out specific tasks relating to the coordination responsibilities. In addition, several attorneys from the Civil Rights Division are involved in reviewing and analyzing proposed rules.

COMPLAINT RESOLUTION AND LEGAL WORKLOAD

Question: You state that you expect the need for legal services to decline -- hence the elimination of 15 positions, or 27 percent.

How many of the 1,800 complaints received in 1984 do you anticipate will be resolved by voluntary compliance? How many fewer cases will go to the attorneys?

Answer: OCR anticipates receiving 1,267 complaints in fiscal year 1984. Of the estimated forty percent that will be investigated, nearly all will be resolved voluntarily. Based on prior year data, we project that less than one percent of complaints received in fiscal year 1984 will require enforcement action. Attorneys usually provide advice and assistance during the course of an investigation as well as during enforcement action. We anticipate that, if our projections concerning complaint receipts hold true, the legal staff will assist OCR in processing approximately the same number of complaints in fiscal year 1984 as in 1983.

Question: What is the current number of cases per attorney in FY '83 as opposed to the 1984 projection?

Answer: We anticipate that the number of complaints which will require some legal assistance will remain essentially the same in both fiscal years 1983 and 1984. Therefore, we will not be reducing the number of attorneys available to provide such assistance. However, due to our emphasis on voluntary compliance and outreach initiatives, such as project reviews, OCR will be able to reduce the number of attorneys needed to provide legal assistance in areas other than complaint resolution.

SURVEY DATA

Question: OCR apparently plans "no general surveys for fiscal year 1984 for the purpose of obtaining compliance information on a program-wide basis."

How can you effectively manage and allocate your resources without having relevant information available to assess the "big picture"?

Answer: OCR does not plan to conduct any general nation-wide surveys of facilities in fiscal year 1984 because survey data now on hand are adequate to meet our planning and resource allocation needs. However, as indicated in our budget justification, a certain percentage of hospitals assisted under the Hill-Burton Act will be surveyed by means of community services assurance reports.

Question: How will you be able to determine who gets a compliance review without survey data?

Answer: OCR will utilize existing survey data as well as other information to target compliance reviews. Recently, OCR conducted general surveys of hospitals and of youth referral and child placement practices. This survey information, as well as the community services assurance reports from Hill-Burton facilities, will be relied on to identify possible compliance problems.

Question: How many recipients are you supposed to be checking up on?

Answer: There are approximately 230,000 group and institutional providers of federally-assisted services that are subject to the nondiscrimination laws that OCR enforces.

REDUCTION IN PERSONNEL

Question: Your budget request for FY '84 reduces the number of permanent positions by 15 for a total of 509 positions. I also understand that your present number of employees is approximately 470, which is about 54 positions below the FY '83 authorized level of 524.

Why are you 10% below your current authorized level?

Answer: The Budget assumes 475 compensable workyears in FY 1983 and we presently project to use that level through the fiscal year. This staffing level will enable OCR to carry out its responsibilities effectively through emphasis on voluntary compliance and outreach and other means of efficiently processing our workload. The FY 1984 budget request reflects this emphasis and brings the level of full time permanent positions more in line with the current number of employees.

Question: How has this factor affected your programs?

Answer: OCR has maintained its commitment to assuring the nondiscriminatory provision of services in HHS-funded programs. Through management efficiencies and new preventive civil rights initiatives, we have been able to carry out the Department's responsibilities in an effective manner.

Question: Why are you asking for a reduction of 15 permanent positions in FY '84?

Answer: Since 1981, OCR has undertaken an innovative and more effective approach which has allowed us to place more emphasis on review, voluntary compliance, and outreach efforts. The need for legal services and other support has diminished due to this renewed emphasis. Our request seeks 15 fewer positions in fiscal year 1984 because of the decreased need for legal services to support areas other than complaint investigation and resolution.

BLOCK GRANTS AND NONDISCRIMINATION

Question: The Office for Civil Rights is in charge of enforcing the nondiscrimination provisions contained in the block grant statutes. While we understand that the implementing regulations in this regard have not yet been issued, the Office does have the responsibility of notifying State Governors whenever discrimination is found to exist in the block grant programs.

Has the Office thus far made any findings of noncompliance?

Answer: To date, OCR has not made any findings of noncompliance under the block grant programs.

Question: If so, what has been the disposition of each finding?

Answer: There have been no findings of noncompliance.

Question: What is the status of regulations with respect to block grants?

Answer: A regulation was approved by former Secretary Schweiker on February 3, 1983. The regulation was then forwarded to the Department of Justice and the EEOC for review and comment. EEOC has forwarded comments. We are currently awaiting comments from the Department of Justice.

PRE-GRANT REVIEWS

Question: Please explain the purpose of your pre-grant reviews in FY '84. Also, please tell us if these reviews include an assessment of whether facilities are in compliance with the physical accessibility requirements of Section 504?

Answer: Through pre-grant reviews, OCR assures that applicants for participation or recertification in the Medicare program are in compliance with civil rights laws. On the basis of desk audits and followup site visits, as necessary, OCR notifies the Health Care Financing Administration as to whether a facility can be cleared for Medicare certification. In the Section 504 area, the reviews focus on procedural aspects of compliance, including whether or not the facility has a Section 504 coordinator; if a self-evaluation is on file and what it concluded; a description of auxiliary aids available; and, policies and procedures regarding communication with persons having sensory impairments. Pre-grant reviews do not specifically address questions concerning physical accessibility. However, analysis of a facility's self-evaluation may raise accessibility issues that require followup. In this event, regional outreach staff work with facilities to help them resolve any physical access problems that have surfaced.

POLICY RESEARCH REDUCTION

Question: You have stated that your Department of Policy Research is and I quote — "The only flexible research authority

available to the Secretary for work on emerging and changing issues of national policy significance. It is used to examine issues that cannot be addressed adequately by individual HHS programs or evaluation authority."

Are we running out of significant issues and problems in HHS? Why then are you requesting a 25 percent reduction in the Health Policy Research Budget?

Answer: The $3.7 million reduction for Policy Research projects is consistent with the Administration's policy to reduce budgets for discretionary programs, especially those that do not provide direct assistance to beneficiaries.

No ongoing projects will be cut because of the more limited funding proposed for FY 1984, although funding for new projects will be more limited than during FY 1982 and FY 1983. The reduction also reflects the phase-down of several large projects—notably the Health Insurance Experiment—as they near completion. These large demonstrations are being replaced by smaller, short-term projects designed to respond to more immediate needs for policy information. Finally, the reduction also reflects an agreement with the Wisconsin Institute for the Study of Poverty that the $1.5 million appropriated for FY 1983 will support research for both FY 1983 and 1984.

INSTITUTE FOR POVERTY RESEARCH

Question: Please expand upon the accomplishments of the Institute for Poverty Research. Why are you not in favor of continuing support for this project?

Answer: The accomplishments of the Institute for Research on Poverty have been numerous and varied in its more than fifteen years of existence. The Institute has performed research on the nature, causes, and cures of poverty in the United States. The wide diversity of the research can be demonstrated by a selection of its recent research monographs:

- Income-Tested Transfer Programs: The Case For and Against (Irwin Garfinkel, editor), 1982.
- A Challenge to Social Security: The Changing Roles of Women and Men in American Society (Richard Burkhauser and Karen Holden, editors), 1980.
- Microeconomic Simulation Models for Public Policy Analysis (Robert Haveman and Devin Hollenbeck, editors), 1980.
- The Politics of Displacement: Racial and Ethnic Transition in Three American Cities (Peter Eisinger), 1980.

Between 1966 and 1974 the Office of Economic Opportunity awarded grants totaling about $10.5 million to the Poverty Institute. Subsequent to transfer of funding responsibility to this Depart-

ment in 1974, another $10.5 million had been spent, for a total of $21 million.

In FY 1982 HHS eliminated the core support for the Institute, since even though proposed research of the Institute was reviewed on a yearly basis, plans were all too often at variance with Department needs. Instead, competitive procurements were used to seek applications nationwide for policy analysis in specific areas of research on poverty. The competitive process worked well. Awards totaling over $500 thousand were made in FY 1982 to three institutions for policy research of this same kind. Researchers at the Institute received nearly $175 thousand in policy research funds in FY 1982.

In FY 1983, appropriation language required the obligation of $1.5 million to continue research on poverty conducted by the Institute for Research on Poverty. By request of, and agreement with, the Institute, this amount will cover both FY 1983 and 1984. The Institute research agenda, developed in consultation with the Office of the Assistant Secretary for Planning and Evaluation, contains the following:

- Relative Economic Status. Examination of the effect of public programs on the incidence of poverty from 1940 - 1980, and the differential effects on various demographic groups.

- Disability Transfers and Impact on Labor Supply. Examination of the relative economic status of the disabled compared with the non-disabled, design of a measure of disability status, and examination of the labor market behavior of disabled women.

- Labor Market and Transfer Program Participation of Hispanic Immigrants and Asian Refugees.

- Research Conference on Poverty. At the 20th anniversary of the war on poverty, an assessment of the impacts, past trends, current conditions, and future directions.

- Research on Labor Markets and Public Assistance. Investigation of labor market strategies to increase employment earnings of low-wage workers.

- Small Grant Program. To include: (1) effect of income eligibility for Medicaid on family behavior; (2) welfare use and its effects on poverty and perceptions of poverty; (3) cost-effectiveness of preventive health activities for the poor; and (4) the role of HMOs in providing care to Medicaid recipients.

WELFARE ADMINISTRATION STUDIES

Question: Please describe the expected accomplishments of the Welfare Administration Studies and specifically, how these will impact on the administration of welfare programs?

Answer: The purpose of research in the Welfare Administration Studies area is to improve the operation of the Aid to

Families with Dependent Children (AFDC) program by working cooperatively with state and local welfare agencies, as well as with appropriate federal agencies. In this way, the Federal government aids state initiatives with both financial and technical assistance. Such support of state welfare reforms is consistent with the Administration's goals of making states more responsible for the testing and implementation of innovative new approaches to the operation of the AFDC program.

The requested funding for the Welfare Administration Studies will support projects that examine ways to facilitate and encourage the transition of welfare recipients to private sector employment. This research will assess the widely-held hypothesis that the prospect of losing medical benefits is a significant impediment to this transition. The particular hypothesis under study is the following: were adequate health insurance coverage made available to some categories of AFDC cases, a sufficient incentive would be created to draw clients off welfare and into private sector employment, thus saving dollars in both the AFDC and Medicaid programs. This health coverage might be made available through formation of state risk sharing pools offering private group health insurance, at considerably less premium costs than there would be with an individual policy. This project will be jointly conducted by health and income security/employment policy staff, bringing to bear the combined field demonstration experiences of both offices—experience not available elsewhere in the Department. Close coordination and sharing of information will be maintained with HHS operating agencies.

HEALTH CARE INCENTIVES REFORM

Question: You have indicated that several health competitive policy projects were completed. Please provide this committee with copies of their final reports and a brief statement for each project on how its results may be useful.

Answer: The policy research program on Health Care Competition/Incentives was established in FY 1982. Except for minor developmental work, none of this research has been completed as of Spring 1983. Nevertheless, preliminary findings and background materials are currently being used in support of, and to refine, the Administration's health incentives strategy; for example, in response to information requests.

Studies undertaken to date include —

- o An examination of the relationship betweeen state Medicaid policy changes and circumstances in the state, and the impact of those changes.

- o An exploration of the implications for Medicaid of the shift to prospective reimbursement under Medicare. Many states use Medicare rules and procedures for reimbursement under Medicare.

- o Development of staging concepts (i.e., degree of severity of illness) in Diognostic Related Groups (DRGs). The project will identify DRGs in which there may be particular problems

with severity of illness and seek ways to refine or improve them.

These studies will produce information for development of policies and reforms concerning reimbursement and related practices of the Medicare and Medicaid programs. Other studies will examine consumer choice in private health care financing and its consequences in order to develop policies that maximize competition and health incentive reform.

Final research reports will be forwarded to the Committee as the studies are completed.

RAND HEALTH INSURANCE STUDY

Question: What is the Rand study -- can you describe its accomplishments to date and those anticipated?

Answer: The Rand Health Insurance Experiment (HIE) is a study in which 2,700 families at six sites have been randomly assigned to health insurance plans with differing coinsurance rates and maximum out-of-pocket medical care expenditure limits. The objectives of the study are to measure the effects of patient cost-sharing on the demand for medical care, the quality of care received under different plans, and the health status of participants. Results of the study have been used in shaping the Department's Health Incentives Reform proposals and in forecasting the economic outcomes of these proposals.

Among the more significant findings to date are the following:

- o Persons fully covered for medical services spend about 50 percent more than those with only an income-related catastrophic plan.
- o Full coverage leads to both more users of care and greater consumption per user for both ambulatory services and hospital admissions.
- o Once patients are admitted to the hospital, type of plan does not significantly influence use of services.
- o Cost sharing affects adult expenditures more than children's—the probability of hospital admission for children does not vary by plan.
- o Dental, mental, and optical service utilization are all substantially influenced by patient cost sharing.

IMPREST FUNDS - INTERNAL CONTROLS

Question: In July 1982, your Inspector General issued a report which indicated the need to improve internal controls over imprest fund activities. Please comment on what your Department has done to address the deficiencies identified in this report.

Answer: Based on the draft audit report, we highlighted the findings and reminded each operating component of the need to follow established procedures. We requested all offices to evaluate the size of their imprest funds and to reduce them where they were found to be excessive. Additionally, we requested each office to review its record and report any fund losses or irregularities that occurred after January 1, 1981.

The Inspector General reviewed 77 of the 1,569 active imprest funds in the department. The 77 funds totaled $1.2 million, or about 50% of the dollar value of all our imprest funds. The major findings included:

- Excessive fund levels.

- Failure to make unannounced audits and cash verifications.

- Inadequate facilities for safekeeping the cash.

- Failure to follow proper procedures for maintaining the funds.

- Inadequate separation of duties.

All offices filed reports with us that they had taken appropriate steps to resolve the deficiencies.

Question: Your request for fiscal year 1984 includes $8,891,000 for facilities engineering. This total includes $357,000 for the initiation of an automated information system. You indicate on page 56 of your justifications that the funds for this initiative will be primarily provided by the elimination of 21 regional office positions because of declining federal construction and federally assisted construction programs.

Will the full implementation of the automated information system allow you to make further reductions in your projected 1984 facilities engineering staff?

Answer: The staffing level is primarily affected by the construction activity level and not automation. Further reductions in FY 1984 will not be possible since the development and implementation of the automated system will take about 2 years. It is not possible at this time to accurately project possible future cuts beyond FY 1984. The FY 1984 ceiling figures in the budget already take into account staffing cuts that can be made with certainty at this time.

Question: Your Inspector General in his last report referred to internal control weaknesses in the administration of construction contracts by the Office of Facilities Engineering. The IG's audit found: (1) inadequate or inconsistent policies and procedures relating to the establishment and modification of guaranteed maximum price contracts; (2) inadequate policies regarding construction manager contracts; (3) lack of pre and post award audits of

construction management contracts; and (4) lack of separation of duties of the contracting and project officer.

What have you done to correct these weaknesses?

Answer: Issues 1, 2 and 3 relate to "Construction Manager" type contracts. A nationwide moratorium against any further contracting of this nature was established on March 6, 1981. Consequently the controls suggested by the IG are no longer required.

New chapters for the Facilities Engineering and Construction (FEC) Manual have been drafted which will convert the present moratorium to a virtual prohibition against further Construction Manager contracts on direct Federal projects, and encourage a more discriminate use by grantees on federally assisted projects.

With respect to item 4, on February 15, 1983, procurement functions of the Office of Facilities Engineering were transferred to the Office of the Deputy Assistant Secretary for Procurement, Assistance and Logistics, thereby eliminating the possibility that the same individual would serve as both the contracting officer and the project officer.

SUBCOMMITTEE RECESS

Senator WEICKER. The subcommittee will stand in recess until April 27 at 8:30 at which time we will begin our public witness hearings.

[Whereupon at 9:40 a.m., Friday, April 15, the subcommittee was recessed, to reconvene at 8:30 a.m., Wednesday, April 27.]

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